

US3822465 (Prod: Tryon Medical Partners, PLLC)

Generated By: KC Joubran

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All time stamps listed in this document are displayed in GMT

US3822465

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Participant ID

US3822465

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

US3822465

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Date of Birth (MMM yyyy)	(b) (6) 1979
Age	41
Age Units	YEARS
Age (Derived)	41
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	True
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 21:27:32

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Date of Informed Consent (<i>dd MMM yyyy</i>)	23 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 21:27:32

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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 21:27:32

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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 21:27:32

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 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 21:27:32

Generated On: 10 Jun 2021 09:58:10

Condition	THYROID NODULE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
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 21:27:32

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Condition	GI BLEED
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Condition	DISC DESICCATION - LOWER SPINE
Start date (dd MMM yyyy)	UN UNK 2004
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:39 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:39
Height (xxx.x)	70.5 in
Weight (xxx.x)	305.8 lb
BMI (xxx.x)	43.34801 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 21:27:32

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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 True

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 21:27:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 146779

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 21:27:32

Generated On: 10 Jun 2021 09:58:10

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 21:27:32

Generated On: 10 Jun 2021 09:58:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 11:48
Temperature (xxx.x)	99.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 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 21:27:32

Generated On: 10 Jun 2021 09:58:10

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 12:45
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 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 21:27:32

Generated On: 10 Jun 2021 09:58:10

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 21:27:32

Generated On: 10 Jun 2021 09:58:10

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 12:25

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 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 OCT 2020
Collection time (00:00-23:59)	11:53 (24 HR)
Collection date and time (derived)	23 OCT 2020 11:53

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:10	23 OCT 2020 12:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

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 09:58:10

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 12:45

PC Open Date & Time

23 OCT 2020 12:45

PC Close Date & Time

23 OCT 2020 15:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 98.6 °F

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

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

PC Time Stamp	23 OCT 2020 17:05
PC Open Date & Time	23 OCT 2020 16:10
PC Close Date & Time	24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

99.2 °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 OCT 2020 20:08

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 OCT 2020 20:26

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 19:42

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

98.6 °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

27 OCT 2020 17:37

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

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

28 OCT 2020 16:27

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

97.3 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

29 OCT 2020 20:29

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 OCT 2020 20:54

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

23 OCT 2020 12:46

PC Open Date & Time

23 OCT 2020 12:45

PC Close Date & Time

23 OCT 2020 15:15

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

23 OCT 2020 17:05

PC Open Date & Time

23 OCT 2020 16:10

PC Close Date & Time

24 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

4

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 OCT 2020 20:08

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

1

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 OCT 2020 20:28

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

26 OCT 2020 19:41

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

27 OCT 2020 17:38

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

28 OCT 2020 16:26

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

29 OCT 2020 20:13

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 12:47
PC Open Date & Time	23 OCT 2020 12:45
PC Close Date & Time	23 OCT 2020 15:15

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 17:06
PC Open Date & Time	23 OCT 2020 16:10
PC Close Date & Time	24 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 14:35
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

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)

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	25 OCT 2020 20:27
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:34
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

		Yes <input type="checkbox"/>
PC Time stamp	27 OCT 2020 17:38	
PC Open Date & Time	27 OCT 2020 12:00	
PC Close Date & Time	28 OCT 2020 11:59	

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 16:27
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 20:13
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 30 OCT 2020 20:54

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 OCT 2020 20:54
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3822465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:22

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 11:38
Temperature (xxx.x)	98.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 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

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 NOV 2020
Time of assessment (00:00-23:59)	13:04 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 13:04
Temperature (xxx.x)	99.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3822465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

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.

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

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) 23 NOV 2020

What was the treatment time? (00:00-23:59) 12:30 (24 HR)

Treatment Date and Time (derived) 23 NOV 2020 12:30

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

What was the frequency of the study treatment dosing? ONCE

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

US3822465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 NOV 2020
Collection time (00:00-23:59)	12:00 (24 HR)
Collection date and time (derived)	23 NOV 2020 12:00

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Collection date (dd MMM yyyy)			23 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:24	23 NOV 2020 12:24
Nasopharyngeal Swab 2	No		

US3822465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

99.1 °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

23 NOV 2020 13:04

PC Open Date & Time

23 NOV 2020 12:50

PC Close Date & Time

23 NOV 2020 15:20

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 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	23 NOV 2020 18:03
PC Open Date & Time	23 NOV 2020 16:15
PC Close Date & Time	24 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

102.1 °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

24 NOV 2020 12:01

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.7 °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

25 NOV 2020 16:04

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

99.1 °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

26 NOV 2020 21:19

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

98.3 °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

27 NOV 2020 20:04

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

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

28 NOV 2020 22:15

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

29 NOV 2020 22:10

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

23 NOV 2020 13:04

PC Open Date & Time

23 NOV 2020 12:50

PC Close Date & Time

23 NOV 2020 15:20

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

23 NOV 2020 18:02

PC Open Date & Time

23 NOV 2020 16:15

PC Close Date & Time

24 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

24 NOV 2020 12:02

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

25 NOV 2020 16:03

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

26 NOV 2020 21:15

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

27 NOV 2020 20:04

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

28 NOV 2020 22:15

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

29 NOV 2020 22:10

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 13:05
PC Open Date & Time	23 NOV 2020 12:50
PC Close Date & Time	23 NOV 2020 15:20

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 18:02
PC Open Date & Time	23 NOV 2020 16:15
PC Close Date & Time	24 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	24 NOV 2020 12:02
PC Open Date & Time	24 NOV 2020 12:00
PC Close Date & Time	25 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

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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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 16:03
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	26 NOV 2020 21:15
PC Open Date & Time	26 NOV 2020 12:00
PC Close Date & Time	27 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	27 NOV 2020 20:05
PC Open Date & Time	27 NOV 2020 12:00
PC Close Date & Time	28 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	28 NOV 2020 22:16
PC Open Date & Time	28 NOV 2020 12:00
PC Close Date & Time	29 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 ☒

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

Yes <input type="checkbox"/>	
PC Time stamp	29 NOV 2020 22:09
PC Open Date & Time	29 NOV 2020 12:00
PC Close Date & Time	30 NOV 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 30 NOV 2020 21:44

PC Open Date & Time 30 NOV 2020 12:00

PC Close Date & Time 01 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

01 DEC 2020 19:48

PC Open Date & Time

01 DEC 2020 12:00

PC Close Date & Time

02 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

03 DEC 2020 07:13

PC Open Date & Time

02 DEC 2020 12:00

PC Close Date & Time

03 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 8

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

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 30 NOV 2020 21:44

PC Open Date & Time 30 NOV 2020 12:00

PC Close Date & Time 01 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 9

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 01 DEC 2020 19:48

PC Open Date & Time 01 DEC 2020 12:00

PC Close Date & Time 02 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 NOV 2020 21:44
PC Open Date & Time	30 NOV 2020 12:00
PC Close Date & Time	01 DEC 2020 11:59

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	01 DEC 2020 19:48
PC Open Date & Time	01 DEC 2020 12:00
PC Close Date & Time	02 DEC 2020 11:59

US3822465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 DEC 2020
Time of assessment (00:00-23:59)	12:45 (24 HR)
Vital Signs Date and Time (derived)	28 DEC 2020 12:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

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.

US3822465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 DEC 2020

Collection time (00:00-23:59)

12:55 (24 HR)

Collection date and time (derived)

28 DEC 2020 12:55

US3822465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 21:27:32

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 DEC 2020 06:51:31
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

27 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

31 DEC 2020 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 JAN 2021 14:06:48
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 04:38:09
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 07:01:51
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 103

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

31 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 07:29:55
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 FEB 2021 12:52:28

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

21 FEB 2021 19:37:30

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

28 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

11 MAR 2021 15:21:16

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

18 MAR 2021 08:16:22

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

21 MAR 2021 20:12:01

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

28 MAR 2021 08:05:30

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

04 APR 2021 00:01:54

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

11 APR 2021 08:37:39

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 APR 2021 07:30:32
Patient Cloud Open Date & Time	18 APR 2021 00:01
Patient Cloud Close Date & Time	22 APR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

25 APR 2021 08:10:33

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 MAY 2021 16:58:15
Patient Cloud Open Date & Time	02 MAY 2021 00:01
Patient Cloud Close Date & Time	06 MAY 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 208

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

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

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

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

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

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

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	15 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 AUG 2021 00:01
Patient Cloud Close Date & Time	02 SEP 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 334

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	24 OCT 2021 00:01
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Patient Cloud Close Date & Time	28 OCT 2021 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	26 DEC 2021 00:01
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 FEB 2022 00:01
Patient Cloud Close Date & Time	10 FEB 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	03 APR 2022 00:01
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Patient Cloud Close Date & Time	07 APR 2022 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

14 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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°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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	02 OCT 2022 00:01
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Patient Cloud Close Date & Time	06 OCT 2022 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

06 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Patient Cloud Open Date & Time	13 NOV 2022 00:01
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Patient Cloud Close Date & Time	17 NOV 2022 23:59
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US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

27 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

11 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

[Patient Cloud Open Date & Time](#)

18 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

29 DEC 2022 23:59

US3822465

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:58:10

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		11 MAR 2021 15:21:04

US3822465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 15:31:05

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 15:31:05

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3822465

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3822465

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Date of Contact	14 DEC 2020
Time of Contact	15:30
Date and Time of Contact (derived)	14 DEC 2020 15:30
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 DEC 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 DEC 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.8 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 DEC 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	17 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 DEC 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Date of Visit 14 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 14 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
Day 5	NA (COVID-19 Negative)	
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3822465

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 DEC 2020
Time of assessment (00:00-23:59)	15:43 (24 HR)
Vital Signs Date and Time (derived)	14 DEC 2020 15:43
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3822465

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 DEC 2020

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

US3822465

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

14 DEC 2020

US3822465

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3822465

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

Form: Unblinding

Data signed: (b) (4) 30 Apr 2021 12:57:13

Generated On: 10 Jun 2021 09:58:10

Date of updated informed consent (dd MMM yyyy) 4 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) 4 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 _____

US3822465

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00-23:59)	12:44 (24 HR)
Collection date and time (derived)	4 JAN 2021 12:44

US3822465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	12:50
Collection Date and Time (derived)	4 JAN 2021 12:50

US3822465

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 12 Mar 2021 19:09:26

Generated On: 10 Jun 2021 09:58:10

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

AEID

Adverse event

FATIGUE

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)

11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

AEID

Adverse event COUGH

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) 11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 16 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☒
Grade 2/Moderate ☐
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

AEID

Adverse event

NASAL CONGESTION

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)

11 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

AEID

Adverse event

METALLIC TASTE IN MOUTH

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)

13 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

AEID

Adverse event

SORE THROAT

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)

14 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

AEID	USA-US126-2021-MRNA-1273-P30
	1000008
Adverse event	SEPSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	11 APR 2021
Hospital Discharge Date (dd MMM yyyy)	14 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT CALLED TO REPORT THAT HE WAS HOSPITALIZED FOR SEPSIS FROM 11APR2021-14-APR2021. MEDICAL RECORDS HAVE BEEN REQUESTED AND SAE WILL BE UPDATED ONCE RECORDS ARE RECEIVED.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

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

Yes ☒

No ☐

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

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER, HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Name of Medication ALEVE

Prophylaxis Yes ☐
No ☒

Indication FEVER, HEADACHE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SORE THROAT, JAW PAIN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		14 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Name of Medication METOPROLOL ER

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

Name of Medication LOSARTAN HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 02 Apr 2021 22:22:21

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 22:22:22

Generated On: 10 Jun 2021 09:58:10

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3822465

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:58:10

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

US3822465

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:58:10

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 ☐

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 12:57:13

Generated On: 10 Jun 2021 09:58:10

SAEID	USA-US126-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 12:57:13

Generated On: 10 Jun 2021 09:58:10

SAEID	USA-US126-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	15/APR/2021 14:47
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

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 12:57:13

Generated On: 10 Jun 2021 09:58:10

SAEID	USA-US126-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	CHRISTINA
Investigator's Last Name	KENNELLY
Site Address: Street	6060 PIEDMONT ROW DRIVE SOUTH
Site Address: City	CHARLOTTE
Site Address: State	NC
Site Address: Postal Code	28210
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	26/APR/2021 11:24
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

US3822465 (Prod: Tryon Medical Partners, PLLC)

US3822465

Form: Participant Creation

Generated On: 10 Jun 2021 09:58:10

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'US3822465'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:03:30

US3822465

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:06

US3822465

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:03:32

US3822465

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[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 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:06

US3822465

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'SCRN'	System	23 Oct 2020 16:34:06

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered (b) (6) 1979'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:03:33

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '41'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'YEARS'	System	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '41'	System	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Male (M)'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'I'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:10

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	Kelly Woodell (b) (4)	26 Oct 2020 22:19:38

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Oct 2020'	System	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2020'	System	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Amendment 3 (3)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:44

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:03:32

US3822465

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:10

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'I'	System	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:58:10

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:37:57

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:53:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:53:22
Data point term sent to Coder	System	02 Nov 2020 14:39:03
User entered 'Seasonal allergies'	(b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2018'	System	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2018'	System	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:38:15

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Thyroid mass, LLT: Thyroid nodule - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:53:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 04:53:21
Data point term sent to Coder	System	02 Nov 2020 14:39:03
User entered 'Thyroid nodule'	(b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2018'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Nov 2020 14:38:40
User entered 'Yes (Y)' reason for change: Data Entry Error	System	02 Nov 2020 14:38:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:38:31
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2018'	System	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2018'	System	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:38:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 07:56:25
' (Site from DM).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	26 Jan 2021 19:20:36
' answered with 'Updated' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment.	(b) (4), (b) (6)	15 Jan 2021 11:11:20
' (Site from DM).		
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 05:04:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 05:04:45
Data point term sent to Coder	System	02 Nov 2020 14:40:04
User entered 'Hypertension'	(b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2015'	System	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2015'	System	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:39:31

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Gastrointestinal haemorrhage, LLT: GI bleed - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 05:04:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 05:04:51
Data point term sent to Coder	System	02 Nov 2020 14:40:05
User entered 'GI Bleed'	(b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2016'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2016'	System	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2016'	System	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2016'	System	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2016'	System	02 Nov 2020 14:40:01

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 05:12:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 05:12:44
Data point term sent to Coder	System	02 Nov 2020 14:41:05
User entered 'Back pain'	(b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2004'	System	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2004'	System	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:40:31

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Intervertebral disc desiccation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	04 Nov 2020 18:59:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Nov 2020 18:59:12
Data point term sent to Coder	System	02 Nov 2020 14:41:07
User entered 'Disc desiccation - lower spine'	(b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'UN UNK 2004'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'Jan 2004'	System	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '2004'	System	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered empty.	System	02 Nov 2020 14:40:51

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Per CDM: "Were vital signs assessed?= Yes", However, Time of assessment and Vital Signs Date and Time were blank. Kindly review and update the data accordingly. Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 10:48:22
Query 'Per CDM: "Were vital signs assessed?= Yes", However, Time of assessment and Vital Signs Date and Time were blank. Kindly review and update the data accordingly. Thankyou.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:20:08
User entered '11:39' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 19:20:03
User opened query 'Per CDM: "Were vital signs assessed?= Yes", However, Time of assessment and Vital Signs Date and Time were blank. Kindly review and update the data accordingly. Thankyou.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:09:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 11:09:10
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	(b) (4), (b) (6)	02 Nov 2020 14:41:34
User opened query 'Data is required. Please provide.' System (Site from System).		02 Nov 2020 14:41:30
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '23 Oct 2020 11:39'	System	23 Nov 2020 19:20:03
User entered empty.	System	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '70.5' in	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30
DataPoint set to visible.	System	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '305.8' lb	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30
DataPoint set to visible.	System	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered '43.34801'	System	02 Nov 2020 14:41:30
DataPoint set to visible.	System	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'kg/m2'	System	02 Nov 2020 14:41:30
DataPoint set to visible.	System	23 Oct 2020 16:34:51

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'bpm'	System	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'breaths/min'	System	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'mmHg'	System	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User entered 'mmHg'	System	02 Nov 2020 14:41:30

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:43:04

US3822465

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	28 Apr 2021 19:43:04

US3822465

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:54

US3822465

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:41:54

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '0'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:43:04
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:42:44

US3822465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:35:05

US3822465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 23OCT2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 09:03:38
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 23OCT2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'Sample was shipped 23OCT2020' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:49:04
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 23OCT2020 is reported under Visit 1 Day 1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:08:37
User entered '23 Oct 2020'	(b) (4), (b) (6)	23 Oct 2020 16:35:05

US3822465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
Un-reviewed for Data Management.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 06:08:28
Reviewed for Data Management.	(b) (4), (b) (6)	02 Nov 2020 06:08:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	23 Oct 2020 16:35:05

US3822465

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'VISIT1'	System	23 Oct 2020 16:35:05

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:08:27

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '146779'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:08:27

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 16:08:27

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37

US3822465

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:43:37
DataPoint set to visible.	System	23 Oct 2020 16:34:44

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

Height

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

[Weight](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

Height

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

Weight

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '11:48'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 11:48'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '99.4' F	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '84'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '15'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '140'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '90'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

Height

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:10

Weight

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:45'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User opened query 'Per CDM: The treatment time on the Exposure CRF is 12: 25 and the Vital Signs Post Dose Time of Assessment is 12:45 which has 20 minutes time gap. Per protocol the post dose vital signs should be collected after 30 minutes of the treatment dosing. 'Please clarify' the post dosing time of assessment and update as needed' (Site from DM). User entered '23 Oct 2020 12:45'	(b) (4), (b) (6)	30 Nov 2020 08:02:15
	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '98.3' F	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '84'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '15'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '118'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '77'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	02 Nov 2020 14:44:50

US3822465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:59

US3822465

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:44:59

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:25'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Oct 2020 12:25'	System	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'ONCE'	System	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 16:36:57

US3822465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:19

US3822465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:19

US3822465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '11:53'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:19

US3822465

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Oct 2020 11:53'	System	02 Nov 2020 14:45:19

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:10'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Oct 2020 12:10'	System	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered empty.	System	02 Nov 2020 14:45:33

US3822465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Kindly update EDC with Safety Call D8 data. Thank you.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 21:19:27
Query 'Kindly update EDC with Safety Call D8 data. Thank you.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 19:23:03
User opened query 'Kindly update EDC with Safety Call D8 data. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:34:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Oct 2020 16:37:04

US3822465

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	23 Oct 2020 16:37:04

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:45:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'a33035d5-b7ab-4596-8704-c314819bc71a'	System	23 Oct 2020 16:45:57
User entered 'Yes (Y)'	System	23 Oct 2020 16:45:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:45:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'a33035d5-b7ab-4596-8704-c314819bc71a'	System	23 Oct 2020 16:45:57
User entered '98.3'	System	23 Oct 2020 16:45:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:45:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'a33035d5-b7ab-4596-8704-c314819bc71a'	System	23 Oct 2020 16:45:57
User entered 'No (N)'	System	23 Oct 2020 16:45:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:45:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'a33035d5-b7ab-4596-8704-c314819bc71a'	System	23 Oct 2020 16:45:57
User entered '23 Oct 2020 12:45'	System	23 Oct 2020 16:45:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 12:45'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 15:15'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:04:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'da4ddd13-1b31-48ae-8a6f-83ddafa48fe6'	System	23 Oct 2020 21:05:17
User entered 'Yes (Y)'	System	23 Oct 2020 21:05:17

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'da4ddd13-1b31-48ae-8a6f-83ddafa48fe6'	System	23 Oct 2020 21:05:17
User entered '98.6'	System	23 Oct 2020 21:05:17

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'da4ddd13-1b31-48ae-8a6f-83ddafa48fe6'	System	23 Oct 2020 21:05:17
User entered 'No (N)'	System	23 Oct 2020 21:05:17

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:15', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'da4ddd13-1b31-48ae-8a6f-83ddafa48fe6'	System	23 Oct 2020 21:05:17
User entered '23 Oct 2020 17:05'	System	23 Oct 2020 21:05:17

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 16:10'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 2'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:03', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3cec6707-f9db-44e6-ac69-75df539672c1'	System	25 Oct 2020 00:08:14
User entered 'Yes (Y)'	System	25 Oct 2020 00:08:14

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:07', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3cec6707-f9db-44e6-ac69-75df539672c1'	System	25 Oct 2020 00:08:14
User entered '99.2'	System	25 Oct 2020 00:08:14

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:10', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3cec6707-f9db-44e6-ac69-75df539672c1'	System	25 Oct 2020 00:08:14
User entered 'No (N)'	System	25 Oct 2020 00:08:14

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3cec6707-f9db-44e6-ac69-75df539672c1'	System	25 Oct 2020 00:08:14
User entered '24 Oct 2020 20:08'	System	25 Oct 2020 00:08:14

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 3'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:28', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac057f4-e62e-4abf-8efa-489ce9ac38dd'	System	26 Oct 2020 00:26:41
User entered 'Yes (Y)'	System	26 Oct 2020 00:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac057f4-e62e-4abf-8efa-489ce9ac38dd'	System	26 Oct 2020 00:26:41
User entered '98.0'	System	26 Oct 2020 00:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:36', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac057f4-e62e-4abf-8efa-489ce9ac38dd'	System	26 Oct 2020 00:26:41
User entered 'No (N)'	System	26 Oct 2020 00:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:39', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac057f4-e62e-4abf-8efa-489ce9ac38dd'	System	26 Oct 2020 00:26:41
User entered '25 Oct 2020 20:26'	System	26 Oct 2020 00:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 4'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:42:31', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b5c4bc91-d271-4411-9fd9-f47bbed4aa04'	System	26 Oct 2020 23:42:47
User entered 'Yes (Y)'	System	26 Oct 2020 23:42:47

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:42:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b5c4bc91-d271-4411-9fd9-f47bbbed4aa04'	System	26 Oct 2020 23:42:47
User entered '97.6'	System	26 Oct 2020 23:42:47

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:42:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b5c4bc91-d271-4411-9fd9-f47bbbed4aa04'	System	26 Oct 2020 23:42:47
User entered 'No (N)'	System	26 Oct 2020 23:42:47

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:42:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b5c4bc91-d271-4411-9fd9-f47bbed4aa04'	System	26 Oct 2020 23:42:47
User entered '26 Oct 2020 19:42'	System	26 Oct 2020 23:42:47

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 5'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddc7df65-6e06-4c88-bdfa-dd941245366b'	System	27 Oct 2020 21:37:49
User entered 'Yes (Y)'	System	27 Oct 2020 21:37:49

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:42', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddc7df65-6e06-4c88-bdfa-dd941245366b'	System	27 Oct 2020 21:37:49
User entered '98.6'	System	27 Oct 2020 21:37:49

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddc7df65-6e06-4c88-bdfa-dd941245366b'	System	27 Oct 2020 21:37:49
User entered 'No (N)'	System	27 Oct 2020 21:37:49

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddc7df65-6e06-4c88-bdfa-dd941245366b'	System	27 Oct 2020 21:37:49
User entered '27 Oct 2020 17:37'	System	27 Oct 2020 21:37:49

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 6'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:27:05', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'afa0ac51-38e0-449f-a3a8-d07211aef1f4'	System	28 Oct 2020 20:27:15
User entered 'Yes (Y)'	System	28 Oct 2020 20:27:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:27:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'afa0ac51-38e0-449f-a3a8-d07211aef1f4'	System	28 Oct 2020 20:27:15
User entered '98.2'	System	28 Oct 2020 20:27:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:27:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'afa0ac51-38e0-449f-a3a8-d07211aef1f4'	System	28 Oct 2020 20:27:15
User entered 'No (N)'	System	28 Oct 2020 20:27:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:27:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'afa0ac51-38e0-449f-a3a8-d07211aef1f4'	System	28 Oct 2020 20:27:15
User entered '28 Oct 2020 16:27'	System	28 Oct 2020 20:27:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 7'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:28:29', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830'	System	30 Oct 2020 00:29:15
User entered 'Yes (Y)'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:28:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830' User entered '97.3'	System	30 Oct 2020 00:29:15
	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:28:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830'	System	30 Oct 2020 00:29:15
User entered 'Yes (Y)'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
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 'No conmeds were taken' (Site from System).	(b) (4), (b) (6)	26 Nov 2020 09:18:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 19:19:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:28:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830'	System	30 Oct 2020 00:29:15
User entered '1'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:28:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830'	System	30 Oct 2020 00:29:15
User entered '0'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:29:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6bd56a06-a40d-4168-a2ed-2a77a78a0830'	System	30 Oct 2020 00:29:15
User entered '29 Oct 2020 20:29'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	30 Oct 2020 00:29:15
User entered 'Day 8'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:53:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '316f6871-792d-4aba-806e-98a9d603e373'	System	31 Oct 2020 00:54:24
User entered 'Yes (Y)'	System	31 Oct 2020 00:54:24

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '316f6871-792d-4aba-806e-98a9d603e373'	System	31 Oct 2020 00:54:24
User entered '98.0'	System	31 Oct 2020 00:54:24

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:15', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '316f6871-792d-4aba-806e-98a9d603e373'	System	31 Oct 2020 00:54:24
User entered 'No (N)'	System	31 Oct 2020 00:54:24

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '316f6871-792d-4aba-806e-98a9d603e373'	System	31 Oct 2020 00:54:24
User entered '30 Oct 2020 20:54'	System	31 Oct 2020 00:54:24

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 12:00'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Temperature_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 00:29:15

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '1654bd24-306f-4866-83c1-4a8ace70c0dc'	System	23 Oct 2020 16:46:58
User entered 'None (1)'	System	23 Oct 2020 16:46:58

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '1654bd24-306f-4866-83c1-4a8ace70c0dc'	System	23 Oct 2020 16:46:58
User entered 'No (N)'	System	23 Oct 2020 16:46:58

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '1654bd24-306f-4866-83c1-4a8ace70c0dc'	System	23 Oct 2020 16:46:58
User entered 'No (N)'	System	23 Oct 2020 16:46:58

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:51', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '1654bd24-306f-4866-83c1-4a8ace70c0dc'	System	23 Oct 2020 16:46:58
User entered 'None (1)'	System	23 Oct 2020 16:46:58

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '1654bd24-306f-4866-83c1-4a8ace70c0dc'	System	23 Oct 2020 16:46:58
User entered '23 Oct 2020 12:46'	System	23 Oct 2020 16:46:58

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 12:45'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 15:15'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e0014b4f-ddd3-44c0-aab8-54f126db1e01'	System	23 Oct 2020 21:05:55
User entered 'None (1)'	System	23 Oct 2020 21:05:55

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:42', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e0014b4f-ddd3-44c0-aab8-54f126db1e01'	System	23 Oct 2020 21:05:55
User entered 'No (N)'	System	23 Oct 2020 21:05:55

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e0014b4f-ddd3-44c0-aab8-54f126db1e01'	System	23 Oct 2020 21:05:55
User entered 'No (N)'	System	23 Oct 2020 21:05:55

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e0014b4f-ddd3-44c0-aab8-54f126db1e01'	System	23 Oct 2020 21:05:55
User entered 'None (1)'	System	23 Oct 2020 21:05:55

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:05:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e0014b4f-ddd3-44c0-aab8-54f126db1e01'	System	23 Oct 2020 21:05:55
User entered '23 Oct 2020 17:05'	System	23 Oct 2020 21:05:55

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 16:10'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 2'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:20', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered 'Does not interfere with activity (2)'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:23', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered 'No (N)'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered 'Yes (Y)'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:29', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered '4'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered 'None (1)'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T20:08:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '80d289ba-5c1d-4d6e-88e5-9190575827f9'	System	25 Oct 2020 00:08:42
User entered '24 Oct 2020 20:08'	System	25 Oct 2020 00:08:42

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 3'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered 'Does not interfere with activity (2)'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered 'No (N)'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:42', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered 'Yes (Y)'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered '1'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:58', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered 'None (1)'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:28:03', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4d69e405-f87f-408f-bce7-b56ccb4d9d49'	System	26 Oct 2020 00:28:05
User entered '25 Oct 2020 20:28'	System	26 Oct 2020 00:28:05

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 4'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:41:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '8599f4b9-192d-4d02-805b-709c11a84957'	System	26 Oct 2020 23:41:23
User entered 'None (1)'	System	26 Oct 2020 23:41:23

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:41:15', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '8599f4b9-192d-4d02-805b-709c11a84957'	System	26 Oct 2020 23:41:23
User entered 'No (N)'	System	26 Oct 2020 23:41:23

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:41:17', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '8599f4b9-192d-4d02-805b-709c11a84957'	System	26 Oct 2020 23:41:23
User entered 'No (N)'	System	26 Oct 2020 23:41:23

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:41:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '8599f4b9-192d-4d02-805b-709c11a84957'	System	26 Oct 2020 23:41:23
User entered 'None (1)'	System	26 Oct 2020 23:41:23

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:41:22', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '8599f4b9-192d-4d02-805b-709c11a84957'	System	26 Oct 2020 23:41:23
User entered '26 Oct 2020 19:41'	System	26 Oct 2020 23:41:23

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 5'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:51', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cd262334-1afe-4f83-98c9-43366f35b9e9'	System	27 Oct 2020 21:38:06
User entered 'None (1)'	System	27 Oct 2020 21:38:06

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:54', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cd262334-1afe-4f83-98c9-43366f35b9e9'	System	27 Oct 2020 21:38:06
User entered 'No (N)'	System	27 Oct 2020 21:38:06

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cd262334-1afe-4f83-98c9-43366f35b9e9'	System	27 Oct 2020 21:38:06
User entered 'No (N)'	System	27 Oct 2020 21:38:06

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:37:59', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cd262334-1afe-4f83-98c9-43366f35b9e9'	System	27 Oct 2020 21:38:06
User entered 'None (1)'	System	27 Oct 2020 21:38:06

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:04', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cd262334-1afe-4f83-98c9-43366f35b9e9'	System	27 Oct 2020 21:38:06
User entered '27 Oct 2020 17:38'	System	27 Oct 2020 21:38:06

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 6'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e02247c0-3773-4199-9406-5714d46b52fe'	System	28 Oct 2020 20:26:41
User entered 'None (1)'	System	28 Oct 2020 20:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e02247c0-3773-4199-9406-5714d46b52fe'	System	28 Oct 2020 20:26:41
User entered 'No (N)'	System	28 Oct 2020 20:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e02247c0-3773-4199-9406-5714d46b52fe'	System	28 Oct 2020 20:26:41
User entered 'No (N)'	System	28 Oct 2020 20:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e02247c0-3773-4199-9406-5714d46b52fe'	System	28 Oct 2020 20:26:41
User entered 'None (1)'	System	28 Oct 2020 20:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e02247c0-3773-4199-9406-5714d46b52fe'	System	28 Oct 2020 20:26:41
User entered '28 Oct 2020 16:26'	System	28 Oct 2020 20:26:41

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 7'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3a234444-33d0-452f-a579-5db3c5c36fb8'	System	30 Oct 2020 00:13:31
User entered 'None (1)'	System	30 Oct 2020 00:13:31

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:17', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3a234444-33d0-452f-a579-5db3c5c36fb8'	System	30 Oct 2020 00:13:31
User entered 'No (N)'	System	30 Oct 2020 00:13:31

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:20', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3a234444-33d0-452f-a579-5db3c5c36fb8'	System	30 Oct 2020 00:13:31
User entered 'No (N)'	System	30 Oct 2020 00:13:31

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:22', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3a234444-33d0-452f-a579-5db3c5c36fb8'	System	30 Oct 2020 00:13:31
User entered 'None (1)'	System	30 Oct 2020 00:13:31

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3a234444-33d0-452f-a579-5db3c5c36fb8'	System	30 Oct 2020 00:13:31
User entered '29 Oct 2020 20:13'	System	30 Oct 2020 00:13:31

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:46:59', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:02', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:05', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:10', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'None (0)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:20', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered 'No (N)'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T12:47:23', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9c4c558b-24b9-4196-b502-bca0b5734fff'	System	23 Oct 2020 16:47:25
User entered '23 Oct 2020 12:47'	System	23 Oct 2020 16:47:25

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 12:45'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 15:15'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:05', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:10', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:17', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'None (0)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:22', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered 'No (N)'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-23T17:06:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ceda68e1-52ad-4f2a-8aa3-a1adf5887c6f'	System	23 Oct 2020 21:06:29
User entered '23 Oct 2020 17:06'	System	23 Oct 2020 21:06:29

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Oct 2020 16:10'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 2'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:46', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'None (0)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered 'No (N)'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-24T14:35:54', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '88c3b4e3-35fb-4e62-a2d6-5e7472f1eba0'	System	24 Oct 2020 18:35:57
User entered '24 Oct 2020 14:35'	System	24 Oct 2020 18:35:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 3'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:54', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'None (0)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:26:58', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'No interference with activity (1)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:01', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'None (0)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:04', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'None (0)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:18', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'No interference with activity (1)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:24', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered 'No (N)'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-25T20:27:31', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6a322222-30b7-4792-ace0-3998c99679d4'	System	26 Oct 2020 00:27:36
User entered '25 Oct 2020 20:27'	System	26 Oct 2020 00:27:36

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 4'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'None (0)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c'	System	26 Oct 2020 23:34:53
User entered 'No (N)'	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-26T19:34:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f7076a96-33a7-45a2-ad0f-858a2316f72c' User entered '26 Oct 2020 19:34'	System	26 Oct 2020 23:34:53
	System	26 Oct 2020 23:34:53

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 5'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:10', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:18', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'None (0)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:22', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered 'No (N)'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-27T17:38:24', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '6049702e-134e-4d8a-bc51-73b101e08b32'	System	27 Oct 2020 21:38:27
User entered '27 Oct 2020 17:38'	System	27 Oct 2020 21:38:27

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 6'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:50', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'None (0)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:26:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered 'No (N)'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-28T16:27:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ad76f7a7-ebf6-4bca-b3ea-909fb88c7605'	System	28 Oct 2020 20:27:04
User entered '28 Oct 2020 16:27'	System	28 Oct 2020 20:27:04

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Oct 2020 16:36:57
User entered 'Day 7'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'No interference with activity (1)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:34', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'None (0)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:36', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'None (0)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'None (0)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:39', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'None (0)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'None (0)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered 'No (N)'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-29T20:13:51', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fde28fe7-f74b-49b4-970a-45187136e484'	System	30 Oct 2020 00:13:54
User entered '29 Oct 2020 20:13'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 16:36:57

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	30 Oct 2020 00:13:54
User entered 'Day 8'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:23', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4850e4cf-3904-4704-a6de-549fd16f1018'	System	31 Oct 2020 00:54:31
User entered 'None (0)'	System	31 Oct 2020 00:54:31

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4850e4cf-3904-4704-a6de-549fd16f1018'	System	31 Oct 2020 00:54:31
User entered '30 Oct 2020 20:54'	System	31 Oct 2020 00:54:31

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 12:00'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	30 Oct 2020 00:13:54
User entered 'Day 8'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:32', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddd306bf-7d27-40f2-9fd2-035d6ea59d58'	System	31 Oct 2020 00:54:37
User entered 'No (N)'	System	31 Oct 2020 00:54:37

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-10-30T20:54:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ddd306bf-7d27-40f2-9fd2-035d6ea59d58'	System	31 Oct 2020 00:54:37
User entered '30 Oct 2020 20:54'	System	31 Oct 2020 00:54:37

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Oct 2020 12:00'	System	30 Oct 2020 00:13:54

US3822465

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '31 Oct 2020 11:59'	System	30 Oct 2020 00:13:54

US3822465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:25

US3822465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '2 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:25

US3822465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:25

US3822465

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:25

US3822465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:55:25

US3822465

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	23 Nov 2020 17:55:25

US3822465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:38

US3822465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:38

US3822465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:38

US3822465

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:38

US3822465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:22
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:55:32

US3822465

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	23 Nov 2020 17:55:32

US3822465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:52

US3822465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:52

US3822465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:52

US3822465

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:20:52

US3822465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:55:38

US3822465

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	23 Nov 2020 17:55:38

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 14DEC2020 is reported under Illness Visit Day 1 in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Dec 2020 10:34:48
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 14DEC2020 is reported under Illness Visit Day 1 in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 13:16:41
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 14DEC2020 is reported under Illness Visit Day 1 in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 16:19:16
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23 NOV 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 10:46:32
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23 NOV 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 19:52:31
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab 1: Sample dated 23 NOV 2020 is reported under Visit 2 Day 29 visit in PPD Central lab, however, the same sample data is missing in EDC. Please review and update under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:08:27

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Nov 2020 18:00:12

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:12

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:12

US3822465

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'VISIT2'	System	23 Nov 2020 18:00:12

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '11:38'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Nov 2020 11:38'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '98.9' F	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '76'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'bpm'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '16'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'breaths/min'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '120'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '84'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '13:04'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Nov 2020 13:04'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '99.1' F	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '80'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'bpm'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '18'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'breaths/min'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '122'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '86'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	23 Nov 2020 19:22:15

US3822465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:24

US3822465

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:24

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'MRNA-1273 OR PLACEBO'	System	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:30'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Nov 2020 12:30'	System	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'ONCE'	System	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'INTRAMUSCULAR'	System	23 Nov 2020 18:00:39

US3822465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36

US3822465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36

US3822465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:00'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:22:36

US3822465

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Nov 2020 12:00'	System	23 Nov 2020 19:22:36

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:24'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '23 Nov 2020 12:24'	System	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered empty.	System	04 Dec 2020 15:24:08

US3822465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:00:45

US3822465

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	23 Nov 2020 18:00:45

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4110a91f-74a1-4e79-9957-23b2f0814a50'	System	23 Nov 2020 18:04:46
User entered 'Yes (Y)'	System	23 Nov 2020 18:04:46

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4110a91f-74a1-4e79-9957-23b2f0814a50'	System	23 Nov 2020 18:04:46
User entered '99.1'	System	23 Nov 2020 18:04:46

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4110a91f-74a1-4e79-9957-23b2f0814a50'	System	23 Nov 2020 18:04:46
User entered 'No (N)'	System	23 Nov 2020 18:04:46

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '4110a91f-74a1-4e79-9957-23b2f0814a50'	System	23 Nov 2020 18:04:46
User entered '23 Nov 2020 13:04'	System	23 Nov 2020 18:04:46

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '23 Nov 2020 12:50'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '23 Nov 2020 15:20'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:03:21', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac6f3ac-8351-4272-a150-71df82194062'	System	23 Nov 2020 23:03:38
User entered 'Yes (Y)'	System	23 Nov 2020 23:03:38

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:03:29', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac6f3ac-8351-4272-a150-71df82194062'	System	23 Nov 2020 23:03:38
User entered '98.7'	System	23 Nov 2020 23:03:38

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:03:32', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac6f3ac-8351-4272-a150-71df82194062'	System	23 Nov 2020 23:03:38
User entered 'No (N)'	System	23 Nov 2020 23:03:38

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:03:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0ac6f3ac-8351-4272-a150-71df82194062'	System	23 Nov 2020 23:03:38
User entered '23 Nov 2020 18:03'	System	23 Nov 2020 23:03:38

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '23 Nov 2020 16:15'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 2'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:29', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered 'Yes (Y)'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered '102.1'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered 'Yes (Y)'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
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 'conmed added' (Site from System).	(b) (4), (b) (6)	11 Dec 2020 10:20:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 15:09:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered '1'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered '0'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '0d6052f1-bcc8-42b5-95e3-82fa2dd99eba'	System	24 Nov 2020 17:02:12
User entered '24 Nov 2020 12:01'	System	24 Nov 2020 17:02:12

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 3'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:04:07', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '206c88cb-2de3-4f5b-a2d2-d358c2ce2a22'	System	25 Nov 2020 21:04:16
User entered 'Yes (Y)'	System	25 Nov 2020 21:04:16

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:04:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '206c88cb-2de3-4f5b-a2d2-d358c2ce2a22'	System	25 Nov 2020 21:04:16
User entered '99.7'	System	25 Nov 2020 21:04:16

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:04:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '206c88cb-2de3-4f5b-a2d2-d358c2ce2a22'	System	25 Nov 2020 21:04:16
User entered 'No (N)'	System	25 Nov 2020 21:04:16

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:04:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '206c88cb-2de3-4f5b-a2d2-d358c2ce2a22'	System	25 Nov 2020 21:04:16
User entered '25 Nov 2020 16:04'	System	25 Nov 2020 21:04:16

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 4'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:16:23', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'af124e98-5de7-40fe-949c-559c760c42df'	System	27 Nov 2020 02:19:51
User entered 'Yes (Y)'	System	27 Nov 2020 02:19:51

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:19:36', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'af124e98-5de7-40fe-949c-559c760c42df'	System	27 Nov 2020 02:19:51
User entered '99.1'	System	27 Nov 2020 02:19:51

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:19:39', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'af124e98-5de7-40fe-949c-559c760c42df'	System	27 Nov 2020 02:19:51
User entered 'No (N)'	System	27 Nov 2020 02:19:51

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:19:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'af124e98-5de7-40fe-949c-559c760c42df'	System	27 Nov 2020 02:19:51
User entered '26 Nov 2020 21:19'	System	27 Nov 2020 02:19:51

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 5'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:03:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f8810817-08ba-429e-ab06-9a62e8d7ae1b'	System	28 Nov 2020 01:04:11
User entered 'Yes (Y)'	System	28 Nov 2020 01:04:11

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:03:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f8810817-08ba-429e-ab06-9a62e8d7ae1b' User entered '98.3'	System	28 Nov 2020 01:04:11
	System	28 Nov 2020 01:04:11

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:03:54', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f8810817-08ba-429e-ab06-9a62e8d7ae1b'	System	28 Nov 2020 01:04:11
User entered 'No (N)'	System	28 Nov 2020 01:04:11

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:07', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f8810817-08ba-429e-ab06-9a62e8d7ae1b'	System	28 Nov 2020 01:04:11
User entered '27 Nov 2020 20:04'	System	28 Nov 2020 01:04:11

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 6'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'dfb03f8f-b714-40c3-83e8-0129b529719b'	System	29 Nov 2020 03:15:40
User entered 'Yes (Y)'	System	29 Nov 2020 03:15:40

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'dfb03f8f-b714-40c3-83e8-0129b529719b'	System	29 Nov 2020 03:15:40
User entered '98.1'	System	29 Nov 2020 03:15:40

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'dfb03f8f-b714-40c3-83e8-0129b529719b'	System	29 Nov 2020 03:15:40
User entered 'No (N)'	System	29 Nov 2020 03:15:40

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:36', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'dfb03f8f-b714-40c3-83e8-0129b529719b'	System	29 Nov 2020 03:15:40
User entered '28 Nov 2020 22:15'	System	29 Nov 2020 03:15:40

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 7'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:17', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78ec35d-382b-4bed-802c-04cbf9ca9ce7'	System	30 Nov 2020 03:10:35
User entered 'Yes (Y)'	System	30 Nov 2020 03:10:35

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:21', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78ec35d-382b-4bed-802c-04cbf9ca9ce7'	System	30 Nov 2020 03:10:35
User entered '98.2'	System	30 Nov 2020 03:10:35

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78ec35d-382b-4bed-802c-04cbf9ca9ce7'	System	30 Nov 2020 03:10:35
User entered 'No (N)'	System	30 Nov 2020 03:10:35

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78ec35d-382b-4bed-802c-04cbf9ca9ce7'	System	30 Nov 2020 03:10:35
User entered '29 Nov 2020 22:10'	System	30 Nov 2020 03:10:35

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '800530f3-247d-4caf-b4b9-233119eec7e4'	System	23 Nov 2020 18:04:57
User entered 'None (1)'	System	23 Nov 2020 18:04:57

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:50', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '800530f3-247d-4caf-b4b9-233119eec7e4'	System	23 Nov 2020 18:04:57
User entered 'No (N)'	System	23 Nov 2020 18:04:57

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '800530f3-247d-4caf-b4b9-233119eec7e4'	System	23 Nov 2020 18:04:57
User entered 'No (N)'	System	23 Nov 2020 18:04:57

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '800530f3-247d-4caf-b4b9-233119eec7e4'	System	23 Nov 2020 18:04:57
User entered 'None (1)'	System	23 Nov 2020 18:04:57

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:04:58', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '800530f3-247d-4caf-b4b9-233119eec7e4'	System	23 Nov 2020 18:04:57
User entered '23 Nov 2020 13:04'	System	23 Nov 2020 18:04:57

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 12:50'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 15:20'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:34', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '48b1867d-6376-41f4-9eeb-73017df00efe'	System	23 Nov 2020 23:02:51
User entered 'None (1)'	System	23 Nov 2020 23:02:51

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:37', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '48b1867d-6376-41f4-9eeb-73017df00efe'	System	23 Nov 2020 23:02:51
User entered 'No (N)'	System	23 Nov 2020 23:02:51

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '48b1867d-6376-41f4-9eeb-73017df00efe'	System	23 Nov 2020 23:02:51
User entered 'No (N)'	System	23 Nov 2020 23:02:51

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '48b1867d-6376-41f4-9eeb-73017df00efe'	System	23 Nov 2020 23:02:51
User entered 'None (1)'	System	23 Nov 2020 23:02:51

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '48b1867d-6376-41f4-9eeb-73017df00efe'	System	23 Nov 2020 23:02:51
User entered '23 Nov 2020 18:02'	System	23 Nov 2020 23:02:51

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 16:15'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 2'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:50', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9a769b76-1587-4395-aaac-85fea3977df4'	System	24 Nov 2020 17:02:30
User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 17:02:30

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9a769b76-1587-4395-aac-85fea3977df4'	System	24 Nov 2020 17:02:30
User entered 'No (N)'	System	24 Nov 2020 17:02:30

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:01:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9a769b76-1587-4395-aac-85fea3977df4'	System	24 Nov 2020 17:02:30
User entered 'No (N)'	System	24 Nov 2020 17:02:30

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:07', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9a769b76-1587-4395-aaac-85fea3977df4'	System	24 Nov 2020 17:02:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	24 Nov 2020 17:02:30

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '9a769b76-1587-4395-aaac-85fea3977df4'	System	24 Nov 2020 17:02:30
User entered '24 Nov 2020 12:02'	System	24 Nov 2020 17:02:30

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 3'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '5de2ffef-36fb-4f0c-84b8-61b678b87ed0'	System	25 Nov 2020 21:03:26
User entered 'Does not interfere with activity (2)'	System	25 Nov 2020 21:03:26

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '5de2ffef-36fb-4f0c-84b8-61b678b87ed0'	System	25 Nov 2020 21:03:26
User entered 'No (N)'	System	25 Nov 2020 21:03:26

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:18', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '5de2ffef-36fb-4f0c-84b8-61b678b87ed0'	System	25 Nov 2020 21:03:26
User entered 'No (N)'	System	25 Nov 2020 21:03:26

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:23', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '5de2ffef-36fb-4f0c-84b8-61b678b87ed0'	System	25 Nov 2020 21:03:26
User entered 'Does not interfere with activity (2)'	System	25 Nov 2020 21:03:26

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '5de2ffef-36fb-4f0c-84b8-61b678b87ed0'	System	25 Nov 2020 21:03:26
User entered '25 Nov 2020 16:03'	System	25 Nov 2020 21:03:26

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 4'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:27', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '13adbd62-4981-49e8-8757-d12e63327c15'	System	27 Nov 2020 02:15:44
User entered 'None (1)'	System	27 Nov 2020 02:15:44

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:29', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '13adbd62-4981-49e8-8757-d12e63327c15'	System	27 Nov 2020 02:15:44
User entered 'No (N)'	System	27 Nov 2020 02:15:44

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:31', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '13adbd62-4981-49e8-8757-d12e63327c15'	System	27 Nov 2020 02:15:44
User entered 'No (N)'	System	27 Nov 2020 02:15:44

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:34', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '13adbd62-4981-49e8-8757-d12e63327c15'	System	27 Nov 2020 02:15:44
User entered 'None (1)'	System	27 Nov 2020 02:15:44

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '13adbd62-4981-49e8-8757-d12e63327c15'	System	27 Nov 2020 02:15:44
User entered '26 Nov 2020 21:15'	System	27 Nov 2020 02:15:44

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 5'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:15', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '20949e3d-aedd-4870-8530-cec3509b33f6'	System	28 Nov 2020 01:04:47
User entered 'None (1)'	System	28 Nov 2020 01:04:47

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:20', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '20949e3d-aedd-4870-8530-cec3509b33f6'	System	28 Nov 2020 01:04:47
User entered 'No (N)'	System	28 Nov 2020 01:04:47

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:27', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '20949e3d-aedd-4870-8530-cec3509b33f6'	System	28 Nov 2020 01:04:47
User entered 'No (N)'	System	28 Nov 2020 01:04:47

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:33', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '20949e3d-aedd-4870-8530-cec3509b33f6'	System	28 Nov 2020 01:04:47
User entered 'Does not interfere with activity (2)'	System	28 Nov 2020 01:04:47

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '20949e3d-aedd-4870-8530-cec3509b33f6'	System	28 Nov 2020 01:04:47
User entered '27 Nov 2020 20:04'	System	28 Nov 2020 01:04:47

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 6'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cb4869f7-f98a-4a59-9ec4-a4beec65154c'	System	29 Nov 2020 03:15:56
User entered 'None (1)'	System	29 Nov 2020 03:15:56

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:42', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cb4869f7-f98a-4a59-9ec4-a4beec65154c'	System	29 Nov 2020 03:15:56
User entered 'No (N)'	System	29 Nov 2020 03:15:56

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cb4869f7-f98a-4a59-9ec4-a4beec65154c'	System	29 Nov 2020 03:15:56
User entered 'No (N)'	System	29 Nov 2020 03:15:56

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cb4869f7-f98a-4a59-9ec4-a4beec65154c'	System	29 Nov 2020 03:15:56
User entered 'None (1)'	System	29 Nov 2020 03:15:56

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:49', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'cb4869f7-f98a-4a59-9ec4-a4beec65154c'	System	29 Nov 2020 03:15:56
User entered '28 Nov 2020 22:15'	System	29 Nov 2020 03:15:56

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 7'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:57', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '277d2171-ed46-496a-bb05-4e780cfe497d'	System	30 Nov 2020 03:10:14
User entered 'None (1)'	System	30 Nov 2020 03:10:14

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:59', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '277d2171-ed46-496a-bb05-4e780cfe497d'	System	30 Nov 2020 03:10:14
User entered 'No (N)'	System	30 Nov 2020 03:10:14

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:05', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '277d2171-ed46-496a-bb05-4e780cfe497d'	System	30 Nov 2020 03:10:14
User entered 'No (N)'	System	30 Nov 2020 03:10:14

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '277d2171-ed46-496a-bb05-4e780cfe497d'	System	30 Nov 2020 03:10:14
User entered 'None (1)'	System	30 Nov 2020 03:10:14

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:10:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '277d2171-ed46-496a-bb05-4e780cfe497d'	System	30 Nov 2020 03:10:14
User entered '29 Nov 2020 22:10'	System	30 Nov 2020 03:10:14

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:03', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:06', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:08', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:10', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'None (0)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered 'No (N)'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T13:05:21', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'e2143255-a828-4ecb-ac17-a09511036a73'	System	23 Nov 2020 18:05:22
User entered '23 Nov 2020 13:05'	System	23 Nov 2020 18:05:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 12:50'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 15:20'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:02', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:04', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:06', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:07', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'None (0)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered 'No (N)'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-23T18:02:22', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '871d0cb3-5c66-44e2-a7b6-46408bc83b7a'	System	23 Nov 2020 23:02:22
User entered '23 Nov 2020 18:02'	System	23 Nov 2020 23:02:22

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '23 Nov 2020 16:15'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 2'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:24', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'Some interference with activity (2)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'Significant; prevents daily activity (3)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'Significant; prevents daily activity (3)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:39', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:47', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'Some interference with activity not requiring medical attention (2)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered 'No (N)'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-24T12:02:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae3ad003-89f9-4bf9-ac39-d09dc38b7e64'	System	24 Nov 2020 17:02:59
User entered '24 Nov 2020 12:02'	System	24 Nov 2020 17:02:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '24 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 3'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:31', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'No interference with activity (1)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:36', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'No interference with activity (1)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:40', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'Some interference with activity (2)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'Some interference with activity (2)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:46', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'None (0)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'None (0)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered 'No (N)'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-25T16:03:59', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '73b14518-e871-4be3-b974-e5b7abef32cb'	System	25 Nov 2020 21:03:59
User entered '25 Nov 2020 16:03'	System	25 Nov 2020 21:03:59

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '25 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 4'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:02', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'None (0)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:06', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'No interference with activity (1)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'No interference with activity (1)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'No interference with activity (1)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:13', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'None (0)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'None (0)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered 'No (N)'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-26T21:15:21', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '76409ba6-3415-4c1f-a3a6-f16aac46c0e3'	System	27 Nov 2020 02:15:24
User entered '26 Nov 2020 21:15'	System	27 Nov 2020 02:15:24

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '26 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 5'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'None (0)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:04:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'Some interference with activity (2)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:06', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'No interference with activity (1)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'Some interference with activity (2)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:11', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'None (0)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:14', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'None (0)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered 'No (N)'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-27T20:05:38', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '909e020f-4f48-4af4-ae64-c6f018e75c64'	System	28 Nov 2020 01:05:41
User entered '27 Nov 2020 20:05'	System	28 Nov 2020 01:05:41

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '27 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 6'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'None (0)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'No interference with activity (1)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:15:57', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'None (0)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:16:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'No interference with activity (1)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:16:02', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'None (0)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:16:03', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'None (0)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:16:06', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered 'No (N)'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-28T22:16:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '418fa521-935a-42c4-8ee8-a4f2cdf5fd64'	System	29 Nov 2020 03:16:15
User entered '28 Nov 2020 22:16'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '28 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	23 Nov 2020 18:00:39
User entered 'Day 7'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:32', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'None (0)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'No interference with activity (1)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:41', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'Some interference with activity (2)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'None (0)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:46', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'None (0)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'None (0)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:50', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered 'No (N)'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-29T22:09:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd4cd6624-c64f-4c30-bf68-7356cd784c4d'	System	30 Nov 2020 03:09:56
User entered '29 Nov 2020 22:09'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '29 Nov 2020 12:00'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Nov 2020 11:59'	System	23 Nov 2020 18:00:39

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	29 Nov 2020 03:16:15
User entered 'Day 8'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f0f9c789-bf93-47c5-a190-cf4167807a88'	System	01 Dec 2020 02:45:00
User entered 'No interference with activity (1)'	System	01 Dec 2020 02:45:00

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:56', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f0f9c789-bf93-47c5-a190-cf4167807a88'	System	01 Dec 2020 02:45:00
User entered '30 Nov 2020 21:44'	System	01 Dec 2020 02:45:00

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Nov 2020 12:00'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '01 Dec 2020 11:59'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	30 Nov 2020 03:09:56
User entered 'Day 9'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7b4ca492-af8a-4823-9dff-14742453a2c5'	System	02 Dec 2020 00:48:51
User entered 'No interference with activity (1)'	System	02 Dec 2020 00:48:51

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7b4ca492-af8a-4823-9dff-14742453a2c5'	System	02 Dec 2020 00:48:51
User entered '01 Dec 2020 19:48'	System	02 Dec 2020 00:48:51

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '01 Dec 2020 12:00'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '02 Dec 2020 11:59'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	01 Dec 2020 02:45:00
User entered 'Day 10'	System	01 Dec 2020 02:45:00

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-03T07:13:12', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fe877e1d-e8f4-4f17-ad5b-992ca69e7549'	System	03 Dec 2020 12:13:18
User entered 'None (0)'	System	03 Dec 2020 12:13:18

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-03T07:13:16', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'fe877e1d-e8f4-4f17-ad5b-992ca69e7549'	System	03 Dec 2020 12:13:18
User entered '03 Dec 2020 07:13'	System	03 Dec 2020 12:13:18

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '02 Dec 2020 12:00'	System	01 Dec 2020 02:45:00

US3822465

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(10)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '03 Dec 2020 11:59'	System	01 Dec 2020 02:45:00

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	30 Nov 2020 03:09:56
User entered 'Day 8'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:44', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f0603fe7-f259-4e19-8e02-9e4d64e31c19'	System	01 Dec 2020 02:44:49
User entered 'No interference with activity (1)'	System	01 Dec 2020 02:44:49

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:46', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'f0603fe7-f259-4e19-8e02-9e4d64e31c19'	System	01 Dec 2020 02:44:49
User entered '30 Nov 2020 21:44'	System	01 Dec 2020 02:44:49

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '30 Nov 2020 12:00'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '01 Dec 2020 11:59'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
Data entry locked.	System	30 Nov 2020 03:09:56
User entered 'Day 9'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7eb7d209-e1c6-437c-8fa7-2aa0bb437084'	System	02 Dec 2020 00:48:56
User entered 'None (0)'	System	02 Dec 2020 00:48:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:50', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7eb7d209-e1c6-437c-8fa7-2aa0bb437084'	System	02 Dec 2020 00:48:56
User entered '01 Dec 2020 19:48'	System	02 Dec 2020 00:48:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '01 Dec 2020 12:00'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:57
User entered '02 Dec 2020 11:59'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	29 Nov 2020 03:16:15
User entered 'Day 8'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:32', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '49572631-7604-4bc4-9dc3-8a58dc8e805c'	System	01 Dec 2020 02:44:38
User entered 'No (N)'	System	01 Dec 2020 02:44:38

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-11-30T21:44:35', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '49572631-7604-4bc4-9dc3-8a58dc8e805c'	System	01 Dec 2020 02:44:38
User entered '30 Nov 2020 21:44'	System	01 Dec 2020 02:44:38

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '30 Nov 2020 12:00'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '01 Dec 2020 11:59'	System	29 Nov 2020 03:16:15

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
Data entry locked.	System	30 Nov 2020 03:09:56
User entered 'Day 9'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

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 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:53', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'df3147c6-832f-4301-a737-07bc3e7d1546'	System	02 Dec 2020 00:48:58
User entered 'No (N)'	System	02 Dec 2020 00:48:58

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-01T19:48:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'df3147c6-832f-4301-a737-07bc3e7d1546'	System	02 Dec 2020 00:48:58
User entered '01 Dec 2020 19:48'	System	02 Dec 2020 00:48:58

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '01 Dec 2020 12:00'	System	30 Nov 2020 03:09:56

US3822465

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 10 Jun 2021 09:58:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 20:33:49
User entered '02 Dec 2020 11:59'	System	30 Nov 2020 03:09:56

US3822465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:28

US3822465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '30 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:28

US3822465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:28

US3822465

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:28

US3822465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:24:31

US3822465

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	04 Dec 2020 15:24:31

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Immunogenicity sample collected on 28DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:51:13
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Immunogenicity sample collected on 28DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:30:29
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Immunogenicity sample collected on 28DEC2020 for the Visit 3 Day 57 Visit, however, there is no data recorded for the Visit 3 Day 57 Visit. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 21:29:19
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 19:50:56
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 15:08:59

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 14 DEC 2020 is reported under Illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the sample has been collected and update the details under appropriate visit or provide clarification, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 05:04:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 15:49:22

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '07 Dec 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:49:22

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:49:22

US3822465

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:49:22

US3822465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:10
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:49:26

US3822465

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:10
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 21:16:31
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 14DEC2020 is reported under Illness Visit in PPD Central lab, however the sample details are missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit, thank you.' (Site from DM).	(b) (4), (b) (6)	24 Dec 2020 05:11:30
User entered 'I'	System	10 Dec 2020 15:49:26

US3822465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:01:47

US3822465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:01:47

US3822465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:01:47

US3822465

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:01:47

US3822465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:01:52

US3822465

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	06 Jan 2021 20:01:52

US3822465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:06

US3822465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:06

US3822465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:06

US3822465

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'VISIT3'	System	06 Jan 2021 20:02:06

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:45'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '28 Dec 2020 12:45'	System	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '88'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'bpm'	System	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '18'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'breaths/min'	System	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '147'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '92'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'mmHg'	System	06 Jan 2021 20:02:40

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41

US3822465

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41

US3822465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:04

US3822465

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:04

US3822465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:15

US3822465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '28 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:15

US3822465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered '12:55'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:15

US3822465

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered '28 Dec 2020 12:55'	System	07 Jan 2021 18:30:15

US3822465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	14 Feb 2021 21:27:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 18:30:22

US3822465

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	07 Jan 2021 18:30:22

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2020-12-20T06:51:17', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '46e11f31-77db-4538-8ca4-416e644004c6'	System	20 Dec 2020 11:51:31
User entered 'No (N)'	System	20 Dec 2020 11:51:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2020-12-20T06:51:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '46e11f31-77db-4538-8ca4-416e644004c6'	System	20 Dec 2020 11:51:31
User entered 'No (N)'	System	20 Dec 2020 11:51:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2020-12-20T06:51:31', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '46e11f31-77db-4538-8ca4-416e644004c6'	System	20 Dec 2020 11:51:31
User entered '20 Dec 2020 06:51:31'	System	20 Dec 2020 11:51:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-01-05T14:06:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ebfe1651-1566-410d-b9df-854a542b6f68'	System	05 Jan 2021 19:06:54
User entered 'No (N)'	System	05 Jan 2021 19:06:54

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-01-05T14:06:45', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ebfe1651-1566-410d-b9df-854a542b6f68'	System	05 Jan 2021 19:06:54
User entered 'No (N)'	System	05 Jan 2021 19:06:54

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-01-05T14:06:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ebfe1651-1566-410d-b9df-854a542b6f68'	System	05 Jan 2021 19:06:54
User entered '05 Jan 2021 14:06:48'	System	05 Jan 2021 19:06:54

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-01-10T04:38:03', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '26e30c5a-79a9-45a6-adb5-cb6e978407b8'	System	10 Jan 2021 09:38:11
User entered 'No (N)'	System	10 Jan 2021 09:38:11

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-01-10T04:38:05', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '26e30c5a-79a9-45a6-adb5-cb6e978407b8'	System	10 Jan 2021 09:38:11
User entered 'No (N)'	System	10 Jan 2021 09:38:11

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-01-10T04:38:09', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '26e30c5a-79a9-45a6-adb5-cb6e978407b8' User entered '10 Jan 2021 04:38:09'	System	10 Jan 2021 09:38:11

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-01-17T07:01:39', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '42098e89-86d4-4ce7-93f7-6259fe95a462'	System	17 Jan 2021 12:01:53
User entered 'No (N)'	System	17 Jan 2021 12:01:53

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-01-17T07:01:48', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '42098e89-86d4-4ce7-93f7-6259fe95a462'	System	17 Jan 2021 12:01:53
User entered 'No (N)'	System	17 Jan 2021 12:01:53

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-01-17T07:01:51', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '42098e89-86d4-4ce7-93f7-6259fe95a462'	System	17 Jan 2021 12:01:53
User entered '17 Jan 2021 07:01:51'	System	17 Jan 2021 12:01:53

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-02-07T07:29:43', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b7742a8f-e06f-4124-a2eb-dfdac3b506a2'	System	07 Feb 2021 12:29:57
User entered 'No (N)'	System	07 Feb 2021 12:29:57

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-02-07T07:29:52', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b7742a8f-e06f-4124-a2eb-dfdac3b506a2'	System	07 Feb 2021 12:29:57
User entered 'No (N)'	System	07 Feb 2021 12:29:57

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-02-07T07:29:55', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b7742a8f-e06f-4124-a2eb-dfdac3b506a2'	System	07 Feb 2021 12:29:57
User entered '07 Feb 2021 07:29:55'	System	07 Feb 2021 12:29:57

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-02-14T12:52:19', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '793706e2-30c5-4265-af6d-8b943d1a31e2'	System	14 Feb 2021 17:52:31
User entered 'No (N)'	System	14 Feb 2021 17:52:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-02-14T12:52:26', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '793706e2-30c5-4265-af6d-8b943d1a31e2'	System	14 Feb 2021 17:52:31
User entered 'No (N)'	System	14 Feb 2021 17:52:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-02-14T12:52:28', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '793706e2-30c5-4265-af6d-8b943d1a31e2'	System	14 Feb 2021 17:52:31
User entered '14 Feb 2021 12:52:28'	System	14 Feb 2021 17:52:31

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-02-21T19:37:25', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '77d3cc08-176e-42af-8467-5df12cede55e'	System	22 Feb 2021 00:37:34
User entered 'No (N)'	System	22 Feb 2021 00:37:34

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-02-21T19:37:28', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '77d3cc08-176e-42af-8467-5df12cede55e'	System	22 Feb 2021 00:37:34
User entered 'No (N)'	System	22 Feb 2021 00:37:34

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-02-21T19:37:30', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '77d3cc08-176e-42af-8467-5df12cede55e'	System	22 Feb 2021 00:37:34
User entered '21 Feb 2021 19:37:30'	System	22 Feb 2021 00:37:34

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-03-11T15:21:11-05:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2c545c89-7ea8-4a7c-80c8-022a77b7182d'	System	11 Mar 2021 20:21:24
User entered 'No (N)'	System	11 Mar 2021 20:21:24

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-03-11T15:21:14-05:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2c545c89-7ea8-4a7c-80c8-022a77b7182d'	System	11 Mar 2021 20:21:24
User entered 'No (N)'	System	11 Mar 2021 20:21:24

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-11T15:21:16-05:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2c545c89-7ea8-4a7c-80c8-022a77b7182d' User entered '11 Mar 2021 15:21:16'	System	11 Mar 2021 20:21:24
	System	11 Mar 2021 20:21:24

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-03-18T08:16:17-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae4faeee-b331-421b-adca-50e0a9514807'	System	18 Mar 2021 12:16:25
User entered 'No (N)'	System	18 Mar 2021 12:16:25

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-03-18T08:16:20-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae4faeee-b331-421b-adca-50e0a9514807'	System	18 Mar 2021 12:16:25
User entered 'No (N)'	System	18 Mar 2021 12:16:25

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-18T08:16:22-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ae4faeee-b331-421b-adca-50e0a9514807'	System	18 Mar 2021 12:16:25
User entered '18 Mar 2021 08:16:22'	System	18 Mar 2021 12:16:25

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-03-21T20:11:52-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78e1c43-4d3b-420a-aae5-4b22f2ce6942'	System	22 Mar 2021 00:12:07
User entered 'No (N)'	System	22 Mar 2021 00:12:07

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-03-21T20:11:59-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78e1c43-4d3b-420a-aae5-4b22f2ce6942'	System	22 Mar 2021 00:12:07
User entered 'No (N)'	System	22 Mar 2021 00:12:07

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-21T20:12:01-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'd78e1c43-4d3b-420a-aae5-4b22f2ce6942'	System	22 Mar 2021 00:12:07
User entered '21 Mar 2021 20:12:01'	System	22 Mar 2021 00:12:07

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-03-28T08:05:21-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b95930ac-cddc-4961-b1ad-f07e23a3742d'	System	28 Mar 2021 12:05:32
User entered 'No (N)'	System	28 Mar 2021 12:05:32

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-03-28T08:05:26-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b95930ac-cddc-4961-b1ad-f07e23a3742d' User entered 'No (N)'	System	28 Mar 2021 12:05:32
	System	28 Mar 2021 12:05:32

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-28T08:05:30-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'b95930ac-cddc-4961-b1ad-f07e23a3742d' User entered '28 Mar 2021 08:05:30'	System	28 Mar 2021 12:05:32
	System	28 Mar 2021 12:05:32

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-04-04T00:01:46-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'c9494348-8bc6-4faa-b3c6-fa8d1f238898'	System	04 Apr 2021 04:02:56
User entered 'No (N)'	System	04 Apr 2021 04:02:56

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-04-04T00:01:51-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'c9494348-8bc6-4faa-b3c6-fa8d1f238898'	System	04 Apr 2021 04:02:56
User entered 'No (N)'	System	04 Apr 2021 04:02:56

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-04T00:01:54-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'c9494348-8bc6-4faa-b3c6-fa8d1f238898'	System	04 Apr 2021 04:02:56
User entered '04 Apr 2021 00:01:54'	System	04 Apr 2021 04:02:56

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-04-11T08:37:32-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3d2a793f-a1bc-472d-8ea4-27b2f1b6a067'	System	11 Apr 2021 12:37:42
User entered 'No (N)'	System	11 Apr 2021 12:37:42

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-04-11T08:37:37-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3d2a793f-a1bc-472d-8ea4-27b2f1b6a067'	System	11 Apr 2021 12:37:42
User entered 'No (N)'	System	11 Apr 2021 12:37:42

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-11T08:37:39-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '3d2a793f-a1bc-472d-8ea4-27b2f1b6a067'	System	11 Apr 2021 12:37:42
User entered '11 Apr 2021 08:37:39'	System	11 Apr 2021 12:37:42

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-04-18T07:29:58-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263'	System	18 Apr 2021 11:30:41
User entered 'Yes (Y)'	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-04-18T07:30:03-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263' User entered 'No (N)'	System	18 Apr 2021 11:30:41
	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-18T07:30:13-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263' User entered 'No (N)'	System	18 Apr 2021 11:30:41
	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-18T07:30:21-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263' User entered 'Yes (Y)'	System	18 Apr 2021 11:30:41
	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Please 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 (67f44057692e4e36)', Time: '2021-04-18T07:30:29-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263'	System	18 Apr 2021 11:30:41
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-18T07:30:32-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '2165e03b-d8c3-43ea-ab0f-f2a5e2708263' User entered '18 Apr 2021 07:30:32'	System	18 Apr 2021 11:30:41
	System	18 Apr 2021 11:30:41

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-04-25T08:10:26-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7ca3fcf2-8e20-4b47-b34e-462b1c9f6823'	System	25 Apr 2021 12:10:36
User entered 'No (N)'	System	25 Apr 2021 12:10:36

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-04-25T08:10:29-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7ca3fcf2-8e20-4b47-b34e-462b1c9f6823'	System	25 Apr 2021 12:10:36
User entered 'No (N)'	System	25 Apr 2021 12:10:36

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-04-25T08:10:33-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: '7ca3fcf2-8e20-4b47-b34e-462b1c9f6823'	System	25 Apr 2021 12:10:36
User entered '25 Apr 2021 08:10:33'	System	25 Apr 2021 12:10:36

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[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 (67f44057692e4e36)', Time: '2021-05-02T16:58:10-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ec0d4594-5f80-44b3-9245-706b50e0a90a'	System	02 May 2021 20:58:18
User entered 'No (N)'	System	02 May 2021 20:58:18

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

Have you been exposed to someone with 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 (67f44057692e4e36)', Time: '2021-05-02T16:58:12-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ec0d4594-5f80-44b3-9245-706b50e0a90a'	System	02 May 2021 20:58:18
User entered 'No (N)'	System	02 May 2021 20:58:18

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-05-02T16:58:15-04:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ec0d4594-5f80-44b3-9245-706b50e0a90a'	System	02 May 2021 20:58:18
User entered '02 May 2021 16:58:15'	System	02 May 2021 20:58:18

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '25 Dec 2022 00:01'	System	20 Nov 2020 13:41:44

US3822465

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:10

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:41:44
Amendment Manager: User entered '29 Dec 2022 23:59'	System	20 Nov 2020 13:41:44

US3822465

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:58:10

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)	29 Apr 2021 12:59:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-11T15:21:02-05:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ed0eea08-b51e-4f6e-9536-8eb9fb186d37'	System	11 Mar 2021 20:21:09
User entered 'No (N)'	System	11 Mar 2021 20:21:09

US3822465

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:58:10

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (67f44057692e4e36)', Time: '2021-03-11T15:21:04-05:00', User OID: 'PatientReportedOutcome (US3822465)', ODM File OID: 'ed0eea08-b51e-4f6e-9536-8eb9fb186d37'	System	11 Mar 2021 20:21:09
User entered '11 Mar 2021 15:21:04'	System	11 Mar 2021 20:21:09

US3822465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:31:05
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 14:49:00

US3822465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:31:05
User entered '19 Jan 2021'	Kelly Woodell (b) (4)	27 Jan 2021 14:49:00

US3822465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:31:05
User entered 'Contact Made (CONTACT MADE)'	Kelly Woodell (b) (4)	27 Jan 2021 14:49:00

US3822465

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:31:05
User entered empty.	Kelly Woodell (b) (4)	27 Jan 2021 14:49:00

US3822465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User signature succeeded.	Christina Kennelly (b) (4)	05 Mar 2021 15:31:05
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	27 Jan 2021 14:49:04

US3822465

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 09:53:41
User entered 'I'	System	27 Jan 2021 14:49:04

US3822465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:51:25

US3822465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:51:25

US3822465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:51:25

US3822465

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:51:25

US3822465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:51:15

US3822465

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:41:57
User entered 'I'	System	23 Feb 2021 18:51:15

US3822465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Chie Hooker (b) (4)	22 Mar 2021 15:25:39

US3822465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '22 Mar 2021'	Chie Hooker (b) (4)	22 Mar 2021 15:25:39

US3822465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Contact Made (CONTACT MADE)'	Chie Hooker (b) (4)	22 Mar 2021 15:25:39

US3822465

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:10

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	Chie Hooker (b) (4)	22 Mar 2021 15:25:39

US3822465

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Chie Hooker (b) (4)	22 Mar 2021 15:25:45

US3822465

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:10

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:46:07
User entered 'I'	System	22 Mar 2021 15:25:45

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:10

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:15:37

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:10

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '15:30'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:15:37

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:10

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:02
User entered '14 Dec 2020 15:30'	System	29 Dec 2020 13:15:37

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:10

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:15:37

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:10

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:02
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:15:37

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered '%'	System	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:10:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:13:55
User entered '12 Dec 2020' reason for change: Data Entry Error	System	29 Dec 2020 14:13:55
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 14:11:29
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered empty.	System	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:29

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Per CDM: Assessment Not Done is checked yet data is present for Day 3. Please review and reconcile. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Jan 2021 06:51:36
Query 'Per CDM: Assessment Not Done is checked yet data is present for Day 3. Please review and reconcile. Thank you.' answered with 'added' (Site from DM).	Kelly Woodell (b) (4) (b) (4)	14 Jan 2021 15:18:38
User entered '0' reason for change: Data Entry Error	Kelly Woodell (b) (4) (b) (4)	14 Jan 2021 15:18:33
User opened query 'Per CDM: Assessment Not Done is checked yet data is present for Day 3. Please review and reconcile. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 05:27:50
User entered '1'	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '99' reason for change: Data Entry Error	(b) (4) Kelly Woodell (b) (4)	14 Jan 2021 15:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered '%'	System	29 Dec 2020 14:15:10
User entered empty.	System	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '98.4' F reason for change: Data Entry Error	Kelly Woodell (b) (4)	14 Jan 2021 15:18:33
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:10
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:11:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered '%'	System	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:34

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 5 (Day 5)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:57
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Dec 2020 14:15:57
User entered '15 Dec 2020' reason for change: Data Entry Error	System	29 Dec 2020 14:15:57
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	29 Dec 2020 14:13:55
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:15:57
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered empty.	System	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:13:55

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered empty.	System	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered empty.	System	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:42

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User entered empty.	System	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:58:10

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:16:51

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 13:16:32

US3822465

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:58:10

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:51:45
User entered '0'	System	29 Dec 2020 13:16:32

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:58:10

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:58:10

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:18
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:22:29

US3822465

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:48
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:48
User entered 'SICKD1'	System	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '15:43'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User entered '14 Dec 2020 15:43'	System	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14
DataPoint set to visible.	System	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14
DataPoint set to visible.	System	28 Dec 2020 15:07:44

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '77'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User entered 'bpm'	System	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '16'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User entered 'breaths/min'	System	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '138'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User entered 'mmHg'	System	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '82'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56
User entered 'mmHg'	System	28 Dec 2020 15:08:14

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56

US3822465

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:10

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:47:56

US3822465

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Christina Kennelly (b) (4)	02 Feb 2021 01:54:57
User entered 'No (N)'	(b) (4)	
	(b) (4), (b) (6)	28 Dec 2020 15:08:19

US3822465

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:03
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	02 Feb 2021 01:55:17
User entered '14 Dec 2020' reason for change: Data Entry Error	Christina Kennelly (b) (4)	02 Feb 2021 01:55:17
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	02 Feb 2021 01:54:57
User entered '14 Nov 2020' reason for change: Data Entry Error	Christina Kennelly (b) (4)	02 Feb 2021 01:54:57
User entered empty.	(b) (4), (b) (6)	28 Dec 2020 15:08:19

US3822465

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:58:10

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:09
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:29

US3822465

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 10 Jun 2021 09:58:10

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:09
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	28 Dec 2020 15:08:29

US3822465

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

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:27

US3822465

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

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:27

US3822465

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

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Clinic (Clinic)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:27

US3822465

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

Form: Visit Date

Generated On: 10 Jun 2021 09:58:10

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User entered 'UNBLND_DECIDE'	System	04 Jan 2021 18:00:27

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:19:45
User entered '0'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:14:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:29

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
User closed query 'Per CDM: Response noted, however field reflects Amendment 5. Please review per IRT and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 19:27:15
Query 'Per CDM: Response noted, however field reflects Amendment 5. Please review per IRT and update accordingly. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 19:59:51
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 19:59:27
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 19:59:27
User opened query 'Per CDM: Response noted, however field reflects Amendment 5. Please review per IRT and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 05:23:57
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 18:38:57
User signature succeeded.	Christina Kennelly (b) (4)	12 Apr 2021 00:19:45
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Subject was unblinded under A5' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:15:28
User entered 'Amendment 5 (Amendment 5)'	(b) (4), (b) (6)	08 Apr 2021 15:14:54
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 15:01:33
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:29

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 16:23:15
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39
	(b) (4)	

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 16:23:15
User entered 'mRNA-1273 (mRNA-1273)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39
	(b) (4)	

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User entered empty.	System	04 Jan 2021 18:00:39

US3822465

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

Form: Unblinding

Generated On: 10 Jun 2021 09:58:10

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:24:05
User entered empty.	System	04 Jan 2021 18:00:39

US3822465

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:47

US3822465

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:47

US3822465

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '12:44'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:47

US3822465

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User entered '4 Jan 2021 12:44'	System	04 Jan 2021 18:00:47

US3822465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:10

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:56

US3822465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:10

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '4 Jan 2021'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:56

US3822465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:10

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '12:50'	Kelly Woodell (b) (4)	04 Jan 2021 18:00:56

US3822465

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:59:08
User entered '4 Jan 2021 12:50'	System	04 Jan 2021 18:00:56

US3822465

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:58:10

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:39:06
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptoms of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9), MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Feb 2021 11:35:00
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptoms of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9), MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' answered with 'Muscle aches, per patient, lasted from 24NOV-30NOV. This is not longer than 7 days so this does not meet reporting criteria. Please see CRIO for this' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 18:49:44
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptoms of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 9), MUSCLE ACHES persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 02:10:34
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Dec 2020 14:20:03
User entered 'No (N)'	(b) (4), (b) (6)	02 Nov 2020 14:45:54

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User closed query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:27:40
' (Site from DM).		
Query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	02 Feb 2021 16:14:27
' answered with 'Subject was not assessed for potential COVID-19 infection. Per PI not related, see CRIO' (Site from DM).		
User opened query 'Per MM, Please confirm if this subject was assessed for potential COVID-19 infection.	(b) (4), (b) (6)	02 Feb 2021 10:10:37
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:45:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:45:20
Data point term sent to Coder	System	29 Dec 2020 14:44:06
User entered 'FATIGUE'	(b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
User entered empty.	System	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
User entered empty.	System	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
User entered '0'	System	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39
User entered '0'	System	29 Dec 2020 14:43:37

US3822465

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:39

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 14:45:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 14:45:21
Data point term sent to Coder	System	29 Dec 2020 14:45:07
User entered 'COUGH'	(b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
User entered empty.	System	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
User entered empty.	System	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
User entered '0'	System	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40
User entered '0'	System	29 Dec 2020 14:44:12

US3822465

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:40

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 14:45:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 14:45:22
Data point term sent to Coder	System	29 Dec 2020 14:45:08
User entered 'NASAL CONGESTION'	(b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
User entered empty.	System	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '18 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
User entered empty.	System	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
User entered '0'	System	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44
User entered '0'	System	29 Dec 2020 14:44:43

US3822465

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:44

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Dysgeusia, LLT: Taste metallic - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Dec 2020 14:46:18
Data point term sent to Coder	(b) (4)	29 Dec 2020 14:46:08
User entered 'METALLIC TASTE IN MOUTH'	System	29 Dec 2020 14:45:17
	(b) (4), (b) (6)	

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '13 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
User entered empty.	System	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
User entered empty.	System	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
User entered '0'	System	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46
User entered '0'	System	29 Dec 2020 14:45:17

US3822465

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	29 Dec 2020 14:46:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Dec 2020 14:46:18
Data point term sent to Coder	System	29 Dec 2020 14:46:08
User entered 'SORE THROAT'	(b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
User entered empty.	System	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
User entered empty.	System	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered 'TYLENOL'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	12 Mar 2021 19:09:26
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
User entered '0'	System	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51
User entered '0'	System	29 Dec 2020 14:45:53

US3822465

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:37:51

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:46:59
User entered 'USA-US126-2021-mRNA-1273-P301000008'	System	15 Apr 2021 18:46:10
User entered 'New'	(b) (4), (b) (6)	15 Apr 2021 18:46:10

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 12:34:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Apr 2021 12:34:19
Data point term sent to Coder	System	15 Apr 2021 12:27:59
User entered 'Sepsis'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:25:58
User closed query 'Per CDM RQ: Site response indicates "data removed"; however the time is recorded for 00:00 (midnight). Please review and reconcile, else confirm time is correct. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 18:24:13
Query 'Per CDM RQ: Site response indicates "data removed"; however the time is recorded for 00:00 (midnight). Please review and reconcile, else confirm time is correct. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 17:51:25
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 17:51:03
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 17:51:03
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 17:51:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User opened query 'Per CDM RQ: Site response indicates "data removed"; however the time is recorded for 00:00 (midnight). Please review and reconcile, else confirm time is correct. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:40:57
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), (b) (6)	22 Apr 2021 16:09:18
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
Query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' answered with 'data removed' (Site from System).	(b) (4), (b) (6)	15 Apr 2021 12:27:30
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	15 Apr 2021 12:27:21
User entered '00:00'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 17:51:03
User entered '11 Apr 2021 00:00'	System	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '14 Apr 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	15 Apr 2021 12:27:48
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Apr 2021 12:27:21
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Apr 2021 12:27:48
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4)	15 Apr 2021 20:51:17
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 22:05:03
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 22:04:47
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)	29 Apr 2021 22:04:41
User opened query 'PV Query: Please provide signs and symptoms associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 22:04:35
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 22:04:29
User opened 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)	29 Apr 2021 22:04:24
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:10:58
User signature succeeded.	Christina Kennelly (b) (4) (b) (4)	15 Apr 2021 20:51:17

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject called to report that he was hospitalized for sepsis from 11APR2021-14-APR2021. Medical records have been requested and SAE will be updated once records are received.'	(b) (4), (b) (6)	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 12:27:21

US3822465

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:58:10

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	15 Apr 2021 12:27:21

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:39:06
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 (24NOV2020), Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Underarm Swelling/Tenderness) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:23:04
Query 'Per DM CLR: Per Diary Dose 2 Day 2 (24NOV2020), Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Underarm Swelling/Tenderness) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'Subject reported during day 36 phone call, Tylenol was taken for fever and headache. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 19:10:50
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 (24NOV2020), Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (Underarm Swelling/Tenderness) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 08:12:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Dec 2020 15:47:22

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	10 Dec 2020 15:50:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 15:50:11
Data point term sent to Coder	System	10 Dec 2020 15:49:00
User entered 'Tylenol'	(b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Per DM CLR: Please note that there are no AE matching this Con Med indication during this timeframe. If the FEVER, HEADACHE are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study of study vaccination, or otherwise meet 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 reactions of FEVER, HEADACHE did not meet the AE reporting criteria.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 08:22:55
' (Site from DM).		
Query 'Per DM CLR: Please note that there are no AE matching this Con Med indication during this timeframe. If the FEVER, HEADACHE are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study of study vaccination, or otherwise meet 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 reactions of FEVER, HEADACHE did not meet the AE reporting criteria.	(b) (4), (b) (6)	27 Jan 2021 19:59:13
' answered with 'solicited adverse reactions of FEVER, HEADACHE did not meet the AE reporting criteria.		
' (Site from DM).		

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there are no AE matching this Con Med indication during this timeframe. If the FEVER, HEADACHE are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study of study vaccination, or otherwise meet 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 reactions of FEVER, HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 18:54:52
User entered 'Fever, headache'	(b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '500'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User entered empty.	System	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User entered empty.	System	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:36
User entered empty.	System	10 Dec 2020 15:48:00

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
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)	10 Dec 2020 18:43:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Dec 2020 18:43:57
Data point term sent to Coder	System	10 Dec 2020 15:48:59
User entered 'Aleve'	(b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Fever, headache'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '220'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User entered empty.	System	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User entered empty.	System	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:58:46
User entered empty.	System	10 Dec 2020 15:48:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	29 Dec 2020 14:48:22
User coded data point as Term Coded data point by User: Coders System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	29 Dec 2020 14:48:22
Data point term sent to Coders	System	29 Dec 2020 14:47:09
User entered 'TYLENOL'	(b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'SORE THROAT, JAW PAIN'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '650'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '15 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User entered empty.	System	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User entered empty.	System	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:59:00
User entered empty.	System	29 Dec 2020 14:46:43

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 19:20:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:20:10
Data point term sent to Coder	System	26 Jan 2021 19:19:03
User entered 'Metoprolol ER'	(b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '100'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'UN Oct 2015'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 19:18:32

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN HCTZ - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	26 Jan 2021 19:21:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 19:21:58
Data point term sent to Coder	System	26 Jan 2021 19:21:06
User entered 'Losartan HCTZ'	(b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Hypertension'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 10:26:01
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:54:20
User entered '100/12.5' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Mar 2021 13:54:14
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 22:26:23
User entered '12.5'	(b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

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

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'UN Oct 2015'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 19:20:13

US3822465

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:58:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	02 Apr 2021 22:22:23
	(b) (4)	
User entered 'No (N)'	Krishna Shah (b) (4)	11 Dec 2020 17:21:43
	(b) (4)	

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:14
User entered 'USA-US126-2021-MRNA-1273-P301000008'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Christina'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Kennelly'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'Charlotte'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'NC'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '28210'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:24:36
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
User entered 'US'	(b) (4) System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:24:47
User entered '1'	System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:14
User entered 'USA-US126-2021-MRNA-1273-P301000008'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Christina'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Kennelly'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'Charlotte'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'NC'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '28210'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:24:36
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
User entered 'US'	(b) (4) System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:24:47
User entered '1'	System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:58:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
User entered '15/Apr/2021 14:47'	(b) (4) System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:58:10

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)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:24:36
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:14
User entered 'USA-US126-2021-MRNA-1273-P301000008'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Yes (Y)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'No (N)'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Christina'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 18:47:19
User entered 'Kennelly'	System	15 Apr 2021 18:46:10

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '6060 Piedmont Row Drive South'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'Charlotte'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered 'NC'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Christina Kennelly (b) (4)	30 Apr 2021 12:57:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 12:55:15
User entered '28210'	Kelly Woodell (b) (4) (b) (4)	30 Apr 2021 12:40:24

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 16:24:36
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 17:11:21
User signature succeeded.	Christina Kennelly (b) (4)	16 Apr 2021 17:57:23
User entered 'US'	(b) (4) System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:10

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	26 Apr 2021 16:24:47
User entered '1'	System	15 Apr 2021 18:47:29

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:58:10

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:25:20
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:33:01
User entered '26/Apr/2021 11:24'	(b) (4) System	26 Apr 2021 16:24:47

US3822465

Folder: SAE USA-US126-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

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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)	30 Apr 2021 12:25:20
User signature succeeded.	Christina Kennelly (b) (4)	28 Apr 2021 06:33:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:24:47