

US3992024 (Prod: University of Chicago)

Generated By: KC Joubran

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US3992024

Form: Participant Creation

Data signed: (b) (4) 25 Feb 2021 22:20:42

Generated On: 12 Aug 2021 13:52:16

[Participant ID](#)

US3992024

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

US3992024

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: Screening

Form: Demographics

Data signed: (b) (4) 25 Feb 2021 22:23:17

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Date of Birth (MMM yyyy)	(b) (6) 1993
Age	27
Age Units	YEARS
Age (Derived)	27
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	True
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 25 Feb 2021 22:23:17

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Date of Informed Consent (<i>dd MMM yyyy</i>)	23 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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) 25 Feb 2021 22:23:17

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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) 25 Feb 2021 22:23:17

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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) 25 Feb 2021 22:23:17

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 25 Feb 2021 22:23:17

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Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 25 Feb 2021 22:23:17

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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	14:30 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:30
Height (<i>xxx.x</i>)	173 cm
Weight (<i>xxx.x</i>)	74.4 kg
BMI (<i>xxx.x</i>)	24.85883 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:17

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 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) 25 Feb 2021 22:23:17

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 25 Feb 2021 22:23:17

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 25 Feb 2021 22:23:18

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

What was the participant's randomization number? 115416

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) 25 Feb 2021 22:23:18

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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) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 14:30
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	23 SEP 2020 15:53
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020

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

Treatment Date and Time (derived) 23 SEP 2020 15:23

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) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 SEP 2020

Collection time (00:00-23:59)

15:05 (24 HR)

Collection date and time (derived)

23 SEP 2020 15:05

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Collection date (dd MMM yyyy)			23 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:07	23 SEP 2020 15:07
Nasopharyngeal Swab 2	Yes	15:07	23 SEP 2020 15:07

US3992024

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐
No ☒

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

PC Time Stamp 23 SEP 2020 15:57

PC Open Date & Time 23 SEP 2020 15:43

PC Close Date & Time 23 SEP 2020 18:13

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.1 °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 SEP 2020 22:32
PC Open Date & Time	23 SEP 2020 19:08
PC Close Date & Time	24 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 20:03

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 12:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

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 ☒

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 SEP 2020 13:18

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 13:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 28 SEP 2020 12:21

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 29 SEP 2020 12:01

PC Open Date & Time 29 SEP 2020 12:00

PC Close Date & Time 30 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 15:57

PC Open Date & Time

23 SEP 2020 15:43

PC Close Date & Time

23 SEP 2020 18:13

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 22:33

PC Open Date & Time

23 SEP 2020 19:08

PC Close Date & Time

24 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 12:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 12:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 13:19

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 13:11

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 12:21

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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 SEP 2020 12:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 15:58
PC Open Date & Time	23 SEP 2020 15:43
PC Close Date & Time	23 SEP 2020 18:13

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 22:33
PC Open Date & Time	23 SEP 2020 19:08
PC Close Date & Time	24 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 12:01
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 12:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 13:19
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2445

EAB) (1725)

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 13:11
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

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 ☒

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 12:21
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2445

EAB) (1725)

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3992024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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)	27 OCT 2020
Time of assessment (00:00-23:59)	12:26 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 12:26
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	27 OCT 2020
Time of assessment (00:00-23:59)	14:14 (24 HR)
Vital Signs Date and Time (derived)	27 OCT 2020 14:14
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input checked="" type="checkbox"/>
If Other, specify	UNKNOWN
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3992024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 OCT 2020

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

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

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) 27 OCT 2020

What was the treatment time? (00:00-23:59) 13:30 (24 HR)

Treatment Date and Time (derived) 27 OCT 2020 13:30

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

US3992024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 OCT 2020

Collection time (00:00-23:59)

12:50 (24 HR)

Collection date and time (derived)

27 OCT 2020 12:50

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Collection date (dd MMM yyyy)			27 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:54	27 OCT 2020 12:54
Nasopharyngeal Swab 2	Yes	12:54	27 OCT 2020 12:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

27 OCT 2020 13:50

PC Close Date & Time

27 OCT 2020 16:20

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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 ☒

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 17:15
PC Open Date & Time	27 OCT 2020 17:15
PC Close Date & Time	28 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

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 ☒

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

28 OCT 2020 12:16

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

96.0 °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

29 OCT 2020 12:05

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

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 ☒

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 12:21

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 31 OCT 2020 15:28

PC Open Date & Time 31 OCT 2020 12:00

PC Close Date & Time 01 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 01 NOV 2020 12:03

PC Open Date & Time 01 NOV 2020 12:00

PC Close Date & Time 02 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☒

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

Yes ☐

No ☒

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

PC Time Stamp 02 NOV 2020 12:01

PC Open Date & Time 02 NOV 2020 12:00

PC Close Date & Time 03 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

27 OCT 2020 13:50

PC Close Date & Time

27 OCT 2020 16:20

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

27 OCT 2020 17:16

PC Open Date & Time

27 OCT 2020 17:15

PC Close Date & Time

28 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

28 OCT 2020 20:59

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

29 OCT 2020 12:05

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

30 OCT 2020 12:21

PC Open Date & Time

30 OCT 2020 12:00

PC Close Date & Time

31 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

31 OCT 2020 15:28

PC Open Date & Time

31 OCT 2020 12:00

PC Close Date & Time

01 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

01 NOV 2020 12:03

PC Open Date & Time

01 NOV 2020 12:00

PC Close Date & Time

02 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

02 NOV 2020 12:01

PC Open Date & Time

02 NOV 2020 12:00

PC Close Date & Time

03 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

27 OCT 2020 13:50

PC Close Date & Time

27 OCT 2020 16:20

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

No ☒

Yes ☐

PC Time stamp	27 OCT 2020 17:16
PC Open Date & Time	27 OCT 2020 17:15
PC Close Date & Time	28 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 21:00
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

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 ☒

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 12:05
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	30 OCT 2020 12:21
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

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 ☒

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	31 OCT 2020 15:29
PC Open Date & Time	31 OCT 2020 12:00
PC Close Date & Time	01 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	01 NOV 2020 12:03
PC Open Date & Time	01 NOV 2020 12:00
PC Close Date & Time	02 NOV 2020 11:59

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 2445

EAB) (1725)

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

Yes <input type="checkbox"/>	
PC Time stamp	02 NOV 2020 12:01
PC Open Date & Time	02 NOV 2020 12:00
PC Close Date & Time	03 NOV 2020 11:59

US3992024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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	VISIT3

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	24 NOV 2020
Time of assessment (00:00-23:59)	15:40 (24 HR)
Vital Signs Date and Time (derived)	24 NOV 2020 15:40
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 NOV 2020

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

US3992024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 NOV 2020

Collection time (00:00-23:59)

15:20 (24 HR)

Collection date and time (derived)

24 NOV 2020 15:20

US3992024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:18

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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="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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2020 00:01
Patient Cloud Close Date & Time	29 DEC 2020 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 14:27:14
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 07:46:14
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 11:07:17
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Have 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

22 JAN 2021 05:16:21

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 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 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"/>
Have 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 checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this 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

01 FEB 2021 06:21:37

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

05 FEB 2021 05:06:08

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

12 FEB 2021 06:01:30

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

23 FEB 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

26 FEB 2021 17:55:15

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 MAR 2021 06:16:30
Patient Cloud Open Date & Time	05 MAR 2021 00:01
Patient Cloud Close Date & Time	09 MAR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

16 MAR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	19 MAR 2021 05:59:38
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 MAR 2021 01:52:34
Patient Cloud Open Date & Time	26 MAR 2021 00:01
Patient Cloud Close Date & Time	30 MAR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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	06 APR 2021 11:49:29
Patient Cloud Open Date & Time	02 APR 2021 00:01
Patient Cloud Close Date & Time	06 APR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 04:48:27
Patient Cloud Open Date & Time	09 APR 2021 00:01
Patient Cloud Close Date & Time	13 APR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 APR 2021 01:45:15
Patient Cloud Open Date & Time	16 APR 2021 00:01
Patient Cloud Close Date & Time	20 APR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 APR 2021 19:47:05
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 09:23:15

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 236

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 243

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 250

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	22 JUN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	14 SEP 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	19 OCT 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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="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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	23 NOV 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	28 DEC 2021 23:59
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US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 488

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

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Date and time of submission

[Patient Cloud Open Date & Time](#)

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15 FEB 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

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22 FEB 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

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

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

Date and time of submission

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01 MAR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

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04 MAR 2022 00:01

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08 MAR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3992024

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

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US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3992024

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Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

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12 APR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

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19 APR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

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Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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="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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 642

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	20 SEP 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

Date and time of submission	
Patient Cloud Open Date & Time	21 OCT 2022 00:01
Patient Cloud Close Date & Time	25 OCT 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

[Patient Cloud Close Date & Time](#)

15 NOV 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2022 23:59

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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="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"/>

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2022 23:59

US3992024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:52:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 06:15:58

US3992024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 20:57:56

Generated On: 12 Aug 2021 13:52:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3992024

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:57:56

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 17:32:08

Generated On: 12 Aug 2021 13:52:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 17:32:08

Generated On: 12 Aug 2021 13:52:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 APR 2021
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 10:55
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 17:32:08

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 APR 2021

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

US3992024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 17:32:08

Generated On: 12 Aug 2021 13:52:16

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

Collection date (dd MMM yyyy)	22 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	11:08 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	22 APR 2021 11:08
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US3992024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 17:32:08

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3992024

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Date of Contact	21 JAN 2021
Time of Contact	10:45
Date and Time of Contact (derived)	21 JAN 2021 10:45
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	19 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	20 JAN 2021	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (2)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 21 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	21 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	87 %
---------------	------

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

Temperature	ND - Not Done
-------------	---------------

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

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

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

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

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Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 21 Jan 2021

Form: Symptom Log (3)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 21 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	22 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.4 F
-------------	--------

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

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

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

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

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Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 21 Jan 2021

Form: Symptom Log (4)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 21 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	23 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.4 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 21 Jan 2021

Form: Symptom Log (5)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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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Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	24 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" 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 21 Jan 2021

Form: Symptom Log (6)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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"/>

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	25 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 21 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	26 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.6 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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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (8)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="checkbox"/>
Day 9	<input checked="" 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 21 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	27 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.3 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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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" 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 21 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	28 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.2 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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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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 21 Jan 2021

Form: Symptom Log (10)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input checked="" 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 21 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	29 JAN 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

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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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input checked="" 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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	30 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.2 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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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input type="radio"/>
	Mild	<input checked="" 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 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 checked="" 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 21 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	31 JAN 2021	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.1 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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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 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 checked="" 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 21 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	01 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	99 %
---------------	------

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

Temperature	98.2 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 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 checked="" 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 21 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	02 FEB 2021
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	100 %
---------------	-------

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

Temperature	98.2 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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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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 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 checked="" 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"/>

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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	03 FEB 2021
------	-------------

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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

	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 21 Jan 2021

Form: Symptom Log (16)

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 15:40:25

Generated On: 12 Aug 2021 13:52:16

Date of Visit	21 JAN 2021
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of Test	21 JAN 2021
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	1

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☒ No ☐

If Yes, provide:

Start Date 21 JAN 2021

End Date 22 JAN 2021

Oxygen Saturation 87 %

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen?

Yes ☐

No ☒

Start Date

End Date

Non-Invasive Ventilation?

Yes ☐

No ☒

Start Date

End Date

Mechanical Ventilation?

Yes ☐

No ☒

Start Date

End Date

ECMO?

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Yes ☐

No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors

Yes ☐

No ☒

Start Date

End Date

Acute Renal Dysfunction?

Yes ☐

No ☒

Start Date

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:16

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Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	23 JAN 2021
Day 5	Yes	25 JAN 2021
Day 7	Yes	27 JAN 2021
Day 9	Yes	29 JAN 2021
Day 14	Yes	03 FEB 2021
Day 21	Yes	10 FEB 2021
Day 28	Yes	19 FEB 2021

US3992024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	SICKD1

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 JAN 2021
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	21 JAN 2021 10:45
Height (xxx.x)	69 in
Weight (xxx.x)	167 lb
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 JAN 2021

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

US3992024

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 JAN 2021

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 FEB 2021
Time of assessment (00:00-23:59)	08:29 (24 HR)
Vital Signs Date and Time (derived)	19 FEB 2021 08:29
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
Temperature (xxx.x)	35.9 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	UNKNOWN
Pulse (xxx)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3992024

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 FEB 2021

US3992024

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

Form: Visit Date

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

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

Visit date (dd MMM yyyy)	04 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
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US3992024

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

Form: Unblinding

Data signed: (b) (4) 15 Apr 2021 04:47:20

Generated On: 12 Aug 2021 13:52:16

Date of updated informed consent (dd MMM yyyy) 04 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) 04 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 _____

US3992024

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

04 JAN 2021

Collection time (00:00-23:59)

14:20 (24 HR)

Collection date and time (derived)

04 JAN 2021 14:20

US3992024

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 25 Feb 2021 22:23:17

Generated On: 12 Aug 2021 13:52:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 JAN 2021
Collection time (00:00 - 23:59)	14:22
Collection Date and Time (derived)	04 JAN 2021 14:22

US3992024

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 25 Feb 2021 22:20:42

Generated On: 12 Aug 2021 13:52:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 17:27:16

Generated On: 12 Aug 2021 13:52:16

AEID	USA-US219-2021-MRNA-1273-P30 1000003
Adverse event	COVID 19
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 checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	19 JAN 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)	04 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 17:27:16

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 17:27:16

Generated On: 12 Aug 2021 13:52:16

AEID

Adverse event

CALF PAIN

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)

27 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

28 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 17:27:16

Generated On: 12 Aug 2021 13:52:16

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	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:	
<hr/>	
Narrative	
<hr/>	
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)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 25 Feb 2021 22:20:43

Generated On: 12 Aug 2021 13:52:16

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

Yes ☒

No ☐

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

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY / DEPRESSION

Dose per administration 60

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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US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	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 APR 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY / DEPRESSION

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	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)		09 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		30 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		17 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY AND DEPRESSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	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)		01 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)		11 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY AND DEPRESSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	12 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	23 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication TYLENOL PM

Prophylaxis Yes ☐
No ☒

Indication COVID 19 (PAIN FROM
HEADACHE, MUSCLE ACHES,
BODY ACHES)

Dose per administration 2

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

Q 6 HRS PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input 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)		21 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		31 JAN 2021
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"/>

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication APIXABAN

Prophylaxis Yes ☒
No ☐

Indication DVT PROPHYLAXIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	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 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

Name of Medication ESCITALOPRAM OXALATE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 31 Mar 2021 21:20:03

Generated On: 12 Aug 2021 13:52:16

	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 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3992024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 25 Feb 2021 22:23:16

Generated On: 12 Aug 2021 13:52:16

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3992024

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:52:16

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

US3992024

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:52:16

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 ☐

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 17:27:17

Generated On: 12 Aug 2021 13:52:16

SAEID	USA-US219-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 17:27:17

Generated On: 12 Aug 2021 13:52:16

SAEID	USA-US219-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	25/JAN/2021 18:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 17:27:17

Generated On: 12 Aug 2021 13:52:16

SAEID	USA-US219-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	04/MAR/2021 14:43
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

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 17:27:17

Generated On: 12 Aug 2021 13:52:16

SAEID	USA-US219-2021-MRNA-1273-P301000003
Serious	Yes <input type="radio"/> No <input checked="" 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 type="radio"/> No <input checked="" 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	KATHLEEN
Investigator's Last Name	MULLANE
Site Address: Street	5841 SOUTH MARYLAND AVE MC 5065
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60637
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	02/APR/2021 16:20
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

US3992024 (Prod: University of Chicago)

US3992024

Form: Participant Creation

Generated On: 12 Aug 2021 13:52:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'US3992024'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 19:24:30

US3992024

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:23:42
	(b) (4)	

US3992024

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '23 SEP 2020'	RWS_ENDPOINT	23 Sep 2020 19:24:31
	ENDPOINT (b) (4)	

US3992024

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Clinic (Clinic)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:23:42
	(b) (4)	

US3992024

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'SCRN'	System	23 Sep 2020 20:23:42

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered (b) (6) 1993'	RWS_ENDPOINT	23 Sep 2020 19:24:32
	ENDPOINT (b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '27'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'YEARS'	System	23 Sep 2020 20:24:06

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '27'	System	23 Sep 2020 20:25:06

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Male (M)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'I'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:52:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Kathleen Mullane (b) (4)	23 Sep 2020 20:24:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '23 Sep 2020'	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'Sep 2020'	System	23 Sep 2020 20:25:06

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '2020'	System	23 Sep 2020 20:25:06

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Amendment 3 (3)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:06
	(b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	RWS_ENDPOINT	23 Sep 2020 19:24:31
	ENDPOINT (b) (4)	

US3992024

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:52:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'I'	System	23 Sep 2020 20:25:36

US3992024

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:25:36
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:52:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:48:59
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying medical condition/diagnosis or split events and record them as separate MHs. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 13:33:36
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:35:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 17:35:34
Data point term sent to Coder	System	09 Nov 2020 17:34:55
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying medical condition/diagnosis or split events and record them as separate MHs. ' answered with 'MH updated' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	09 Nov 2020 17:34:50
Coding entries removed.	Karen Cornelius (b) (4) (b) (4)	09 Nov 2020 17:34:34
User entered 'Anxiety' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	09 Nov 2020 17:34:34
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying medical condition/diagnosis or split events and record them as separate MHs. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 04:31:37
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Anxiety depression - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 15:50:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Oct 2020 15:50:44
Data point term sent to Coder	System	04 Oct 2020 15:49:50

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

[Condition](#)

Audit	User	Time (GMT)
User entered 'anxiety / depression'	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:49:20

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'un UNK 2013'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:20
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:20
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:20
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	04 Oct 2020 15:49:20
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:20
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'Jan 2013'	System	04 Oct 2020 15:49:20

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '2013'	System	04 Oct 2020 15:49:20

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	04 Oct 2020 15:49:20

US3992024

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	04 Oct 2020 15:49:20

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 15:50:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Oct 2020 15:50:44
	(b) (4)	
Data point term sent to Coder	System	04 Oct 2020 15:49:50
User entered 'tonsillectomy'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'un UNK 2004'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'un UNK 2004'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:49:46
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'Jan 2004'	System	04 Oct 2020 15:49:46

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '2004'	System	04 Oct 2020 15:49:46

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'Jan 2004'	System	04 Oct 2020 15:49:46

US3992024

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '2004'	System	04 Oct 2020 15:49:46

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 17:51:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 17:51:35
	(b) (4)	
Data point term sent to Coder	System	09 Nov 2020 17:35:57
User entered 'Depression'	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'un UNK 2013'	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	09 Nov 2020 17:35:14
	(b) (4)	

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'Jan 2013'	System	09 Nov 2020 17:35:14

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '2013'	System	09 Nov 2020 17:35:14

US3992024

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	09 Nov 2020 17:35:14

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Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	09 Nov 2020 17:35:14

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '23 Sep 2020'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '14:30'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '23 Sep 2020 14:30'	System	04 Oct 2020 15:50:51

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '173' cm	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	
DataPoint set to visible.	System	23 Sep 2020 20:25:36

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '74.4' kg	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	
DataPoint set to visible.	System	23 Sep 2020 20:25:36

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '24.85883'	System	04 Oct 2020 15:50:51
DataPoint set to visible.	System	23 Sep 2020 20:25:36

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'kg/m2'	System	04 Oct 2020 15:50:51
DataPoint set to visible.	System	23 Sep 2020 20:25:36

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 09:12:33
Query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' answered with 'data entry error corrected' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	09 Nov 2020 17:36:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4) (b) (4)	09 Nov 2020 17:36:09
User opened query 'Re-Query :Per CDM: Response noted, kindly consider updating the unit as Blank as Temperature is ND. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:53:39
User closed query 'Per CDM: Per CCG v2.0 pages 23-24 , when Screening and Visit1 are done on the same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP on Screening CRF. Please also update Route of measurement as ND as Route is not required.Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 11:53:39
Query 'Per CDM: Per CCG v2.0 pages 23-24 , when Screening and Visit1 are done on the same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP on Screening CRF. Please also update Route of measurement as ND as Route is not required.Thank you.' answered with 'data removed per query ' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	24 Oct 2020 15:16:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4) (b) (4)	24 Oct 2020 15:16:21

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User opened query 'Per CDM: Per CCG v2.0 pages 23-24 , when Screening and Visit1 are done on the same day, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP and DIASTOLIC BP on Screening CRF. Please also update Route of measurement as ND as Route is not required.Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 10:19:57
User entered '36.3' C	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:50:51

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered 'Other (Other)'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered 'tympanic'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered '76'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'bpm'	System	04 Oct 2020 15:50:51

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered '20'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'breaths/min'	System	04 Oct 2020 15:50:51

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered '140'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'mmHg'	System	04 Oct 2020 15:50:51

US3992024

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4)	24 Oct 2020 15:16:21
	(b) (4)	
User entered '74'	Karen Cornelius (b) (4)	04 Oct 2020 15:50:51
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'mmHg'	System	04 Oct 2020 15:50:51

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16

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Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16

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Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:07
	(b) (4)	

US3992024

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '23 Sep 2020'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:07
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

[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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

[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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'I'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:52:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	04 Oct 2020 15:51:45
	(b) (4)	

US3992024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:25:59

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:25:59

US3992024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Clinic (Clinic)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:25:59

US3992024

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'VISIT1'	System	23 Sep 2020 20:25:59

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 19:29:21

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '115416'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 19:29:21

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Sep 2020 19:29:21

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10

US3992024

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4)	
	Kathleen Mullane (b) (4)	23 Sep 2020 20:26:10
	(b) (4)	
DataPoint set to visible.	System	23 Sep 2020 20:25:06

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '14:30'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 14:30'	System	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '36.3' C	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'tympanic'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '76'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'bpm'	System	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM). Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'ncs' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 10:44:09
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM). User entered '20'	Karen Cornelius (b) (4) (b) (4)	17 Nov 2020 15:10:23
	(b) (4), (b) (6)	12 Nov 2020 15:21:20
	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'breaths/min'	System	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '140'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '74'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:52:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:52:42

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:53'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 15:53'	System	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '36.7' C	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'temporal'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '60'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'bpm'	System	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '16'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'breaths/min'	System	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '132'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '73'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	04 Oct 2020 15:53:27

US3992024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:39

US3992024

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:39

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'MRNA-1273 OR PLACEBO'	System	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:23'	(b) (4) Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 15:23'	System	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Right Arm (RIGHT ARM)'	Kathleen Mullane (b) (4)	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'ONCE'	System	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'INTRAMUSCULAR'	System	23 Sep 2020 20:29:30

US3992024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:17:06

US3992024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:17:06

US3992024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:05'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:17:06

US3992024

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 15:05'	System	24 Sep 2020 15:17:06

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Cornelius (b) (4) (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:07'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 15:07'	System	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Cornelius (b) (4) (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:07'	(b) (4) Karen Cornelius (b) (4)	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '23 Sep 2020 15:07'	System	24 Sep 2020 15:16:48

US3992024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:53:47

US3992024

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	04 Oct 2020 15:53:47

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:20', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'bd41c238-e78a-432d-8169-6dcb69fc1a1d'	System	23 Sep 2020 20:57:37
User entered 'Yes (Y)'	System	23 Sep 2020 20:57:37

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'bd41c238-e78a-432d-8169-6dcb69fc1a1d'	System	23 Sep 2020 20:57:37
User entered '98.0'	System	23 Sep 2020 20:57:37

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'bd41c238-e78a-432d-8169-6dcb69fc1a1d'	System	23 Sep 2020 20:57:37
User entered 'No (N)'	System	23 Sep 2020 20:57:37

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'bd41c238-e78a-432d-8169-6dcb69fc1a1d'	System	23 Sep 2020 20:57:37
User entered '23 Sep 2020 15:57'	System	23 Sep 2020 20:57:37

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 15:43'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 18:13'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:32:23', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '59cad1fd-b624-46f8-bd9c-ba6a6e137cfd'	System	24 Sep 2020 03:32:57
User entered 'Yes (Y)'	System	24 Sep 2020 03:32:57

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:32:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '59cad1fd-b624-46f8-bd9c-ba6a6e137cfd' User entered '96.1'	System	24 Sep 2020 03:32:57
	System	24 Sep 2020 03:32:57

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:32:49', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '59cad1fd-b624-46f8-bd9c-ba6a6e137cfd'	System	24 Sep 2020 03:32:57
User entered 'No (N)'	System	24 Sep 2020 03:32:57

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:32:54', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '59cad1fd-b624-46f8-bd9c-ba6a6e137cfd'	System	24 Sep 2020 03:32:57
User entered '23 Sep 2020 22:32'	System	24 Sep 2020 03:32:57

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 19:08'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 2'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T20:03:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'cca14689-aa2b-45f5-8fca-1c86d29b583c'	System	25 Sep 2020 01:03:28
User entered 'Yes (Y)'	System	25 Sep 2020 01:03:28

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T20:03:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'cca14689-aa2b-45f5-8fca-1c86d29b583c'	System	25 Sep 2020 01:03:28
User entered '97.2'	System	25 Sep 2020 01:03:28

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T20:03:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'cca14689-aa2b-45f5-8fca-1c86d29b583c'	System	25 Sep 2020 01:03:28
User entered 'No (N)'	System	25 Sep 2020 01:03:28

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T20:03:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'cca14689-aa2b-45f5-8fca-1c86d29b583c'	System	25 Sep 2020 01:03:28
User entered '24 Sep 2020 20:03'	System	25 Sep 2020 01:03:28

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 3'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:42', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2da594a5-778c-4546-9e22-1678b7100bad'	System	25 Sep 2020 17:01:49
User entered 'Yes (Y)'	System	25 Sep 2020 17:01:49

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2da594a5-778c-4546-9e22-1678b7100bad' User entered '98.0'	System	25 Sep 2020 17:01:49
	System	25 Sep 2020 17:01:49

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:48', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2da594a5-778c-4546-9e22-1678b7100bad'	System	25 Sep 2020 17:01:49
User entered 'No (N)'	System	25 Sep 2020 17:01:49

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:50', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2da594a5-778c-4546-9e22-1678b7100bad'	System	25 Sep 2020 17:01:49
User entered '25 Sep 2020 12:00'	System	25 Sep 2020 17:01:49

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 4'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:18:55', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a74d58a8-aa8f-48e3-946d-2044f3acc070'	System	27 Sep 2020 18:10:59
User entered 'No (N)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:18:56', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a74d58a8-aa8f-48e3-946d-2044f3acc070'	System	27 Sep 2020 18:10:59
User entered 'No (N)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:18:58', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a74d58a8-aa8f-48e3-946d-2044f3acc070'	System	27 Sep 2020 18:10:59
User entered '26 Sep 2020 13:18'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 5'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:11', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c6a275fa-db30-43ab-bdfb-47f3364a9ae0'	System	27 Sep 2020 18:11:25
User entered 'Yes (Y)'	System	27 Sep 2020 18:11:25

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c6a275fa-db30-43ab-bdfb-47f3364a9ae0'	System	27 Sep 2020 18:11:25
User entered '98.1'	System	27 Sep 2020 18:11:25

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:19', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c6a275fa-db30-43ab-bdfb-47f3364a9ae0'	System	27 Sep 2020 18:11:25
User entered 'No (N)'	System	27 Sep 2020 18:11:25

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:20', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c6a275fa-db30-43ab-bdfb-47f3364a9ae0'	System	27 Sep 2020 18:11:25
User entered '27 Sep 2020 13:11'	System	27 Sep 2020 18:11:25

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 6'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:07', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fcb10f55-13dc-49b6-9009-ab5ee176f354'	System	28 Sep 2020 17:21:14
User entered 'No (N)'	System	28 Sep 2020 17:21:14

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fcb10f55-13dc-49b6-9009-ab5ee176f354'	System	28 Sep 2020 17:21:14
User entered 'No (N)'	System	28 Sep 2020 17:21:14

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fcb10f55-13dc-49b6-9009-ab5ee176f354'	System	28 Sep 2020 17:21:14
User entered '28 Sep 2020 12:21'	System	28 Sep 2020 17:21:14

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 7'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '5a29aef8-cdb1-428e-9e51-f56deeb76ee3'	System	29 Sep 2020 17:01:36
User entered 'No (N)'	System	29 Sep 2020 17:01:36

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '5a29aef8-cdb1-428e-9e51-f56deeb76ee3'	System	29 Sep 2020 17:01:36
User entered 'No (N)'	System	29 Sep 2020 17:01:36

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '5a29aef8-cdb1-428e-9e51-f56deeb76ee3'	System	29 Sep 2020 17:01:36
User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:36

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8f0f26f-5b15-4843-973c-7c79ffc8da92'	System	23 Sep 2020 20:57:55
User entered 'None (1)'	System	23 Sep 2020 20:57:55

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:43', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8f0f26f-5b15-4843-973c-7c79ffc8da92'	System	23 Sep 2020 20:57:55
User entered 'No (N)'	System	23 Sep 2020 20:57:55

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:44', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8f0f26f-5b15-4843-973c-7c79ffc8da92'	System	23 Sep 2020 20:57:55
User entered 'No (N)'	System	23 Sep 2020 20:57:55

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:47', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8f0f26f-5b15-4843-973c-7c79ffc8da92'	System	23 Sep 2020 20:57:55
User entered 'None (1)'	System	23 Sep 2020 20:57:55

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:50', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8f0f26f-5b15-4843-973c-7c79ffc8da92'	System	23 Sep 2020 20:57:55
User entered '23 Sep 2020 15:57'	System	23 Sep 2020 20:57:55

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 15:43'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 18:13'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:02', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1b4f0cb6-2bcd-4c71-af86-148dc8f3d02e'	System	24 Sep 2020 03:33:39
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 03:33:39

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1b4f0cb6-2bcd-4c71-af86-148dc8f3d02e'	System	24 Sep 2020 03:33:39
User entered 'No (N)'	System	24 Sep 2020 03:33:39

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1b4f0cb6-2bcd-4c71-af86-148dc8f3d02e'	System	24 Sep 2020 03:33:39
User entered 'No (N)'	System	24 Sep 2020 03:33:39

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:33', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1b4f0cb6-2bcd-4c71-af86-148dc8f3d02e'	System	24 Sep 2020 03:33:39
User entered 'None (1)'	System	24 Sep 2020 03:33:39

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:36', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1b4f0cb6-2bcd-4c71-af86-148dc8f3d02e'	System	24 Sep 2020 03:33:39
User entered '23 Sep 2020 22:33'	System	24 Sep 2020 03:33:39

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 19:08'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 2'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:00:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '56a45f40-c6a1-4313-a1a4-bc0a772f295b'	System	24 Sep 2020 17:01:26
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Sep 2020 17:01:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:00:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '56a45f40-c6a1-4313-a1a4-bc0a772f295b'	System	24 Sep 2020 17:01:26
User entered 'No (N)'	System	24 Sep 2020 17:01:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:00:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '56a45f40-c6a1-4313-a1a4-bc0a772f295b'	System	24 Sep 2020 17:01:26
User entered 'No (N)'	System	24 Sep 2020 17:01:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:00:49', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '56a45f40-c6a1-4313-a1a4-bc0a772f295b'	System	24 Sep 2020 17:01:26
User entered 'None (1)'	System	24 Sep 2020 17:01:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:00:58', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '56a45f40-c6a1-4313-a1a4-bc0a772f295b'	System	24 Sep 2020 17:01:26
User entered '24 Sep 2020 12:00'	System	24 Sep 2020 17:01:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 3'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:55', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4c6a1010-0b09-4684-a66b-11aebd5a827f'	System	25 Sep 2020 17:02:00
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 17:02:00

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:56', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4c6a1010-0b09-4684-a66b-11aebd5a827f'	System	25 Sep 2020 17:02:00
User entered 'No (N)'	System	25 Sep 2020 17:02:00

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:57', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4c6a1010-0b09-4684-a66b-11aebd5a827f'	System	25 Sep 2020 17:02:00
User entered 'No (N)'	System	25 Sep 2020 17:02:00

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:00:59', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4c6a1010-0b09-4684-a66b-11aebd5a827f'	System	25 Sep 2020 17:02:00
User entered 'None (1)'	System	25 Sep 2020 17:02:00

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:01', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4c6a1010-0b09-4684-a66b-11aebd5a827f'	System	25 Sep 2020 17:02:00
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:00

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 4'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:07', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '60e6dbc0-d30c-45f9-b917-df3894fa5274'	System	27 Sep 2020 18:10:59
User entered 'None (1)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '60e6dbc0-d30c-45f9-b917-df3894fa5274'	System	27 Sep 2020 18:10:59
User entered 'No (N)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '60e6dbc0-d30c-45f9-b917-df3894fa5274'	System	27 Sep 2020 18:10:59
User entered 'No (N)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '60e6dbc0-d30c-45f9-b917-df3894fa5274'	System	27 Sep 2020 18:10:59
User entered 'None (1)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:16', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '60e6dbc0-d30c-45f9-b917-df3894fa5274'	System	27 Sep 2020 18:10:59
User entered '26 Sep 2020 13:19'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 5'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '9dd4b3d5-1481-43d8-a3c0-5bcf0a0d7df4'	System	27 Sep 2020 18:11:37
User entered 'None (1)'	System	27 Sep 2020 18:11:37

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '9dd4b3d5-1481-43d8-a3c0-5bcf0a0d7df4'	System	27 Sep 2020 18:11:37
User entered 'No (N)'	System	27 Sep 2020 18:11:37

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '9dd4b3d5-1481-43d8-a3c0-5bcf0a0d7df4'	System	27 Sep 2020 18:11:37
User entered 'No (N)'	System	27 Sep 2020 18:11:37

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '9dd4b3d5-1481-43d8-a3c0-5bcf0a0d7df4'	System	27 Sep 2020 18:11:37
User entered 'None (1)'	System	27 Sep 2020 18:11:37

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '9dd4b3d5-1481-43d8-a3c0-5bcf0a0d7df4'	System	27 Sep 2020 18:11:37
User entered '27 Sep 2020 13:11'	System	27 Sep 2020 18:11:37

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 6'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:16', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c749000e-b7a3-44c5-ae60-cedcb5b654f2'	System	28 Sep 2020 17:21:26
User entered 'None (1)'	System	28 Sep 2020 17:21:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:17', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c749000e-b7a3-44c5-ae60-cedcb5b654f2'	System	28 Sep 2020 17:21:26
User entered 'No (N)'	System	28 Sep 2020 17:21:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c749000e-b7a3-44c5-ae60-cedcb5b654f2'	System	28 Sep 2020 17:21:26
User entered 'No (N)'	System	28 Sep 2020 17:21:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:19', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c749000e-b7a3-44c5-ae60-cedcb5b654f2'	System	28 Sep 2020 17:21:26
User entered 'None (1)'	System	28 Sep 2020 17:21:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c749000e-b7a3-44c5-ae60-cedcb5b654f2'	System	28 Sep 2020 17:21:26
User entered '28 Sep 2020 12:21'	System	28 Sep 2020 17:21:26

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 7'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1ce77633-a104-4616-923f-279c61013a46'	System	29 Sep 2020 17:01:43
User entered 'None (1)'	System	29 Sep 2020 17:01:43

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:20', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1ce77633-a104-4616-923f-279c61013a46'	System	29 Sep 2020 17:01:43
User entered 'No (N)'	System	29 Sep 2020 17:01:43

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1ce77633-a104-4616-923f-279c61013a46'	System	29 Sep 2020 17:01:43
User entered 'No (N)'	System	29 Sep 2020 17:01:43

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:22', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1ce77633-a104-4616-923f-279c61013a46'	System	29 Sep 2020 17:01:43
User entered 'None (1)'	System	29 Sep 2020 17:01:43

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1ce77633-a104-4616-923f-279c61013a46'	System	29 Sep 2020 17:01:43
User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:43

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:57', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:57:59', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:01', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:04', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'None (0)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered 'No (N)'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T15:58:11', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a14611e8-1a15-49db-afe1-5bc70b9c00ee'	System	23 Sep 2020 20:58:15
User entered '23 Sep 2020 15:58'	System	23 Sep 2020 20:58:15

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 15:43'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 18:13'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 1, after vaccination (at home)'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:39', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:42', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:45', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:48', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:49', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'None (0)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:51', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered 'No (N)'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-23T22:33:53', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3db39549-96aa-4123-9a05-7200df0b5971'	System	24 Sep 2020 03:33:57
User entered '23 Sep 2020 22:33'	System	24 Sep 2020 03:33:57

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '23 Sep 2020 19:08'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 2'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:02', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:04', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:07', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:08', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'None (0)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered 'No (N)'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-24T12:01:13', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0a467c6a-4872-41d0-bdd4-acc98f2dd06c'	System	24 Sep 2020 17:01:54
User entered '24 Sep 2020 12:01'	System	24 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '24 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 3'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:04', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:07', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:08', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'None (0)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered 'No (N)'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-25T12:01:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ee814e96-17da-4780-a026-e8d64f4be773'	System	25 Sep 2020 17:02:26
User entered '25 Sep 2020 12:01'	System	25 Sep 2020 17:02:26

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '25 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 4'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:19', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:20', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:22', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'None (0)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:50', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered 'No (N)'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-26T13:19:52', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'f4ce5b6d-6c5c-4f27-9c05-1586a51a2cd5'	System	27 Sep 2020 18:10:59
User entered '26 Sep 2020 13:19'	System	27 Sep 2020 18:10:59

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '26 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 5'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:36', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:37', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:38', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:39', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:40', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:41', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'None (0)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:43', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered 'No (N)'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-27T13:11:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa42a736-e736-467d-9a02-daf141fbb368'	System	27 Sep 2020 18:11:49
User entered '27 Sep 2020 13:11'	System	27 Sep 2020 18:11:49

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 6'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'None (0)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:33', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered 'No (N)'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-28T12:21:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '00e7c8e1-f5ef-40c8-be2c-2398d0dbcbeb'	System	28 Sep 2020 17:21:37
User entered '28 Sep 2020 12:21'	System	28 Sep 2020 17:21:37

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	23 Sep 2020 20:29:30
User entered 'Day 7'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'None (0)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:33', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered 'No (N)'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-09-29T12:01:34', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0055eb17-595f-4be6-a5d7-a8829354232c'	System	29 Sep 2020 17:01:54
User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:54

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Sep 2020 12:00'	System	23 Sep 2020 20:29:30

US3992024

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Sep 2020 11:59'	System	23 Sep 2020 20:29:30

US3992024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:54:33

US3992024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '30 Sep 2020'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:54:33

US3992024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:54:33

US3992024

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:54:33

US3992024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:54:41

US3992024

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	04 Oct 2020 15:54:41

US3992024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Oct 2020 14:45:06

US3992024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '07 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	08 Oct 2020 14:45:06

US3992024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	08 Oct 2020 14:45:06

US3992024

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	08 Oct 2020 14:45:06

US3992024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	08 Oct 2020 14:45:20

US3992024

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	08 Oct 2020 14:45:20

US3992024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:11:46

US3992024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '14 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:11:46

US3992024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:11:46

US3992024

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:11:46

US3992024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	20 Oct 2020 14:11:33

US3992024

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	20 Oct 2020 14:11:33

US3992024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:33

US3992024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:33

US3992024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Clinic (Clinic)'	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:33

US3992024

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'VISIT2'	System	27 Oct 2020 19:12:33

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Cornelius (b) (4) (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '12:26'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 12:26'	System	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '37.1' C	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '67'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'bpm'	System	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Respiratory Rate (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 07:50:01
Query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'ncs' (Site from DM).	Karen Cornelius (b) (4)	14 Dec 2020 12:01:09
User opened query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 11:28:53
User entered '18'	Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'breaths/min'	System	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '134'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '66'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	28 Oct 2020 15:36:15

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Cornelius (b) (4) (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '14:14'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 14:14'	System	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '36.7' C	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '76'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'bpm'	System	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.'	(b) (4), (b) (6)	19 Nov 2020 10:44:39
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.'	Karen Cornelius (b) (4)	17 Nov 2020 15:10:56
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.'	(b) (4)	
Query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.'	(b) (4)	
User opened query 'Per CDM: Per CCG V2.0 page 50, Respiratory Rate \geq 17 (breaths/min) is considered out of range value. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.'	(b) (4), (b) (6)	12 Nov 2020 15:22:20
User entered '18'	Karen Cornelius (b) (4)	28 Oct 2020 15:36:54
	(b) (4)	

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'breaths/min'	System	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '125'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '68'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	28 Oct 2020 15:36:54

US3992024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:06

US3992024

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:06

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'MRNA-1273 OR PLACEBO'	System	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4)	
	Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02
	(b) (4)	

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '13:30'	(b) (4)	
	Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02
	(b) (4)	

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 13:30'	System	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Kathleen Mullane (b) (4)	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'ONCE'	System	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:52:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'INTRAMUSCULAR'	System	27 Oct 2020 19:12:02

US3992024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:26

US3992024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:26

US3992024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '12:50'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:26

US3992024

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 12:50'	System	28 Oct 2020 15:37:26

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Oct 2020'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Cornelius (b) (4) (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '12:54'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 12:54'	System	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Cornelius (b) (4) (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '12:54'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '27 Oct 2020 12:54'	System	28 Oct 2020 15:37:51

US3992024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:29:16

US3992024

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	28 Oct 2020 15:29:16

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 13:50'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 16:20'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:15:49', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '323cff09-b9ff-4efc-bf0d-8b5a78f87049'	System	27 Oct 2020 22:16:39
User entered 'No (N)'	System	27 Oct 2020 22:16:39

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:15:51', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '323cff09-b9ff-4efc-bf0d-8b5a78f87049'	System	27 Oct 2020 22:16:39
User entered 'No (N)'	System	27 Oct 2020 22:16:39

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:15:53', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '323cff09-b9ff-4efc-bf0d-8b5a78f87049'	System	27 Oct 2020 22:16:39
User entered '27 Oct 2020 17:15'	System	27 Oct 2020 22:16:39

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 17:15'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 2'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T12:16:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'e53e4d7b-8d75-4409-9ebc-1b291f4d68d4'	System	28 Oct 2020 17:16:36
User entered 'No (N)'	System	28 Oct 2020 17:16:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T12:16:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'e53e4d7b-8d75-4409-9ebc-1b291f4d68d4'	System	28 Oct 2020 17:16:36
User entered 'Yes (Y)'	System	28 Oct 2020 17:16:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
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 'patient contacted and stated no medication was taken' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 07:47:53
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).	Karen Cornelius (b) (4)	17 Nov 2020 15:09:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T12:16:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'e53e4d7b-8d75-4409-9ebc-1b291f4d68d4'	(b) (4)	
User entered '1'	System	28 Oct 2020 17:16:36
	System	28 Oct 2020 17:16:36
	System	28 Oct 2020 17:16:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T12:16:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'e53e4d7b-8d75-4409-9ebc-1b291f4d68d4' User entered '0'	System	28 Oct 2020 17:16:36
	System	28 Oct 2020 17:16:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T12:16:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'e53e4d7b-8d75-4409-9ebc-1b291f4d68d4'	System	28 Oct 2020 17:16:36
User entered '28 Oct 2020 12:16'	System	28 Oct 2020 17:16:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 3'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:04:42', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '83cee7fa-e2c7-4a0d-ae99-3fe7c6f91342'	System	29 Oct 2020 17:06:01
User entered 'Yes (Y)'	System	29 Oct 2020 17:06:01

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:22', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '83cee7fa-e2c7-4a0d-ae99-3fe7c6f91342'	System	29 Oct 2020 17:06:01
User entered '96.0'	System	29 Oct 2020 17:06:01

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '83cee7fa-e2c7-4a0d-ae99-3fe7c6f91342'	System	29 Oct 2020 17:06:01
User entered 'No (N)'	System	29 Oct 2020 17:06:01

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '83cee7fa-e2c7-4a0d-ae99-3fe7c6f91342'	System	29 Oct 2020 17:06:01
User entered '29 Oct 2020 12:05'	System	29 Oct 2020 17:06:01

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 4'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2fb48df3-ddf5-4f9b-8000-974160c621f1'	System	30 Oct 2020 17:21:18
User entered 'No (N)'	System	30 Oct 2020 17:21:18

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2fb48df3-ddf5-4f9b-8000-974160c621f1'	System	30 Oct 2020 17:21:18
User entered 'No (N)'	System	30 Oct 2020 17:21:18

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '2fb48df3-ddf5-4f9b-8000-974160c621f1'	System	30 Oct 2020 17:21:18
User entered '30 Oct 2020 12:21'	System	30 Oct 2020 17:21:18

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 5'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd15d16dd-2f5b-4a81-8c50-cea1f810e1fa'	System	31 Oct 2020 20:28:36
User entered 'No (N)'	System	31 Oct 2020 20:28:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd15d16dd-2f5b-4a81-8c50-cea1f810e1fa'	System	31 Oct 2020 20:28:36
User entered 'No (N)'	System	31 Oct 2020 20:28:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd15d16dd-2f5b-4a81-8c50-cea1f810e1fa'	System	31 Oct 2020 20:28:36
User entered '31 Oct 2020 15:28'	System	31 Oct 2020 20:28:36

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 6'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:11', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4341d95e-8738-4dc7-be65-819e79ba6d94'	System	01 Nov 2020 18:03:17
User entered 'No (N)'	System	01 Nov 2020 18:03:17

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:13', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4341d95e-8738-4dc7-be65-819e79ba6d94'	System	01 Nov 2020 18:03:17
User entered 'No (N)'	System	01 Nov 2020 18:03:17

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '4341d95e-8738-4dc7-be65-819e79ba6d94'	System	01 Nov 2020 18:03:17
User entered '01 Nov 2020 12:03'	System	01 Nov 2020 18:03:17

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 7'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'be3430e2-3d14-409b-9132-f5ce26b7c5a5'	System	02 Nov 2020 18:01:11
User entered 'No (N)'	System	02 Nov 2020 18:01:11

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'be3430e2-3d14-409b-9132-f5ce26b7c5a5'	System	02 Nov 2020 18:01:11
User entered 'No (N)'	System	02 Nov 2020 18:01:11

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:07', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'be3430e2-3d14-409b-9132-f5ce26b7c5a5'	System	02 Nov 2020 18:01:11
User entered '02 Nov 2020 12:01'	System	02 Nov 2020 18:01:11

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 13:50'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 16:20'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:15:56', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6ae3af78-feca-45a7-af41-54be1fbe94ed'	System	27 Oct 2020 22:16:41
User entered 'Does not interfere with activity (2)'	System	27 Oct 2020 22:16:41

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:15:58', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6ae3af78-feca-45a7-af41-54be1fbe94ed'	System	27 Oct 2020 22:16:41
User entered 'No (N)'	System	27 Oct 2020 22:16:41

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:01', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6ae3af78-feca-45a7-af41-54be1fbe94ed'	System	27 Oct 2020 22:16:41
User entered 'No (N)'	System	27 Oct 2020 22:16:41

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6ae3af78-feca-45a7-af41-54be1fbe94ed'	System	27 Oct 2020 22:16:41
User entered 'None (1)'	System	27 Oct 2020 22:16:41

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6ae3af78-feca-45a7-af41-54be1fbe94ed' User entered '27 Oct 2020 17:16'	System	27 Oct 2020 22:16:41
	System	27 Oct 2020 22:16:41

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 17:15'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 2'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:38', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd2f79936-717c-4294-820f-b10ba73f0b01'	System	29 Oct 2020 01:59:52
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	29 Oct 2020 01:59:52

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:41', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd2f79936-717c-4294-820f-b10ba73f0b01'	System	29 Oct 2020 01:59:52
User entered 'No (N)'	System	29 Oct 2020 01:59:52

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:43', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd2f79936-717c-4294-820f-b10ba73f0b01'	System	29 Oct 2020 01:59:52
User entered 'No (N)'	System	29 Oct 2020 01:59:52

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd2f79936-717c-4294-820f-b10ba73f0b01'	System	29 Oct 2020 01:59:52
User entered 'None (1)'	System	29 Oct 2020 01:59:52

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:48', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'd2f79936-717c-4294-820f-b10ba73f0b01'	System	29 Oct 2020 01:59:52
User entered '28 Oct 2020 20:59'	System	29 Oct 2020 01:59:52

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 3'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '07dbc71f-5cdb-4f3d-875f-b4e0c037c236'	System	29 Oct 2020 17:06:11
User entered 'Does not interfere with activity (2)'	System	29 Oct 2020 17:06:11

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:33', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '07dbc71f-5cdb-4f3d-875f-b4e0c037c236'	System	29 Oct 2020 17:06:11
User entered 'No (N)'	System	29 Oct 2020 17:06:11

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:34', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '07dbc71f-5cdb-4f3d-875f-b4e0c037c236'	System	29 Oct 2020 17:06:11
User entered 'No (N)'	System	29 Oct 2020 17:06:11

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '07dbc71f-5cdb-4f3d-875f-b4e0c037c236'	System	29 Oct 2020 17:06:11
User entered 'None (1)'	System	29 Oct 2020 17:06:11

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:37', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '07dbc71f-5cdb-4f3d-875f-b4e0c037c236'	System	29 Oct 2020 17:06:11
User entered '29 Oct 2020 12:05'	System	29 Oct 2020 17:06:11

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 4'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:19', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0b19bd6c-f9f5-4706-be59-b077f6a822e8'	System	30 Oct 2020 17:21:28
User entered 'None (1)'	System	30 Oct 2020 17:21:28

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0b19bd6c-f9f5-4706-be59-b077f6a822e8'	System	30 Oct 2020 17:21:28
User entered 'No (N)'	System	30 Oct 2020 17:21:28

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:22', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0b19bd6c-f9f5-4706-be59-b077f6a822e8'	System	30 Oct 2020 17:21:28
User entered 'No (N)'	System	30 Oct 2020 17:21:28

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0b19bd6c-f9f5-4706-be59-b077f6a822e8'	System	30 Oct 2020 17:21:28
User entered 'None (1)'	System	30 Oct 2020 17:21:28

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '0b19bd6c-f9f5-4706-be59-b077f6a822e8'	System	30 Oct 2020 17:21:28
User entered '30 Oct 2020 12:21'	System	30 Oct 2020 17:21:28

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 5'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c8db13a3-c74f-4b46-8a09-e6b2c1222646'	System	31 Oct 2020 20:28:48
User entered 'None (1)'	System	31 Oct 2020 20:28:48

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:36', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c8db13a3-c74f-4b46-8a09-e6b2c1222646'	System	31 Oct 2020 20:28:48
User entered 'No (N)'	System	31 Oct 2020 20:28:48

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:38', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c8db13a3-c74f-4b46-8a09-e6b2c1222646'	System	31 Oct 2020 20:28:48
User entered 'No (N)'	System	31 Oct 2020 20:28:48

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:41', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c8db13a3-c74f-4b46-8a09-e6b2c1222646'	System	31 Oct 2020 20:28:48
User entered 'None (1)'	System	31 Oct 2020 20:28:48

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:44', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c8db13a3-c74f-4b46-8a09-e6b2c1222646'	System	31 Oct 2020 20:28:48
User entered '31 Oct 2020 15:28'	System	31 Oct 2020 20:28:48

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 6'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:17', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b47c26df-e98e-48ab-81d7-0e5b2d2a8d7c'	System	01 Nov 2020 18:03:24
User entered 'None (1)'	System	01 Nov 2020 18:03:24

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b47c26df-e98e-48ab-81d7-0e5b2d2a8d7c'	System	01 Nov 2020 18:03:24
User entered 'No (N)'	System	01 Nov 2020 18:03:24

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:19', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b47c26df-e98e-48ab-81d7-0e5b2d2a8d7c'	System	01 Nov 2020 18:03:24
User entered 'No (N)'	System	01 Nov 2020 18:03:24

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:20', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b47c26df-e98e-48ab-81d7-0e5b2d2a8d7c'	System	01 Nov 2020 18:03:24
User entered 'None (1)'	System	01 Nov 2020 18:03:24

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:22', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b47c26df-e98e-48ab-81d7-0e5b2d2a8d7c'	System	01 Nov 2020 18:03:24
User entered '01 Nov 2020 12:03'	System	01 Nov 2020 18:03:24

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 7'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8832e0be-4a94-4816-a14f-13fb274093ab'	System	02 Nov 2020 18:01:25
User entered 'None (1)'	System	02 Nov 2020 18:01:25

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8832e0be-4a94-4816-a14f-13fb274093ab'	System	02 Nov 2020 18:01:25
User entered 'No (N)'	System	02 Nov 2020 18:01:25

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8832e0be-4a94-4816-a14f-13fb274093ab'	System	02 Nov 2020 18:01:25
User entered 'No (N)'	System	02 Nov 2020 18:01:25

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8832e0be-4a94-4816-a14f-13fb274093ab'	System	02 Nov 2020 18:01:25
User entered 'None (1)'	System	02 Nov 2020 18:01:25

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8832e0be-4a94-4816-a14f-13fb274093ab'	System	02 Nov 2020 18:01:25
User entered '02 Nov 2020 12:01'	System	02 Nov 2020 18:01:25

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 13:50'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 16:20'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 1, after vaccination (at home)'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:08', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:11', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:13', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'None (0)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:17', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered 'No (N)'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-27T17:16:18', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '23bf77d5-c7de-4e8d-9591-a0129248ec2d'	System	27 Oct 2020 22:16:42
User entered '27 Oct 2020 17:16'	System	27 Oct 2020 22:16:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '27 Oct 2020 17:15'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 2'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:53', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'No interference with activity (1)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T20:59:58', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'No interference with activity (1)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:16', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'None (0)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'No interference with activity (1)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'None (0)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'None (0)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered 'No (N)'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-28T21:00:38', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ec6265e9-19e1-4ad6-be63-9af8f8100447'	System	29 Oct 2020 02:00:42
User entered '28 Oct 2020 21:00'	System	29 Oct 2020 02:00:42

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '28 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 3'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:40', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:41', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:42', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:43', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:44', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'None (0)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:48', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered 'No (N)'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-29T12:05:49', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '40967469-5ca9-41c9-9e44-0a34b704d7ee'	System	29 Oct 2020 17:06:17
User entered '29 Oct 2020 12:05'	System	29 Oct 2020 17:06:17

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '29 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 4'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'None (0)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:35', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered 'No (N)'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-30T12:21:36', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1fd990e9-a7e1-4b91-b898-999b4f893039'	System	30 Oct 2020 17:21:41
User entered '30 Oct 2020 12:21'	System	30 Oct 2020 17:21:41

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '30 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 5'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:50', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:52', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:53', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:55', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:56', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:28:58', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'None (0)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:29:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered 'No (N)'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-10-31T15:29:02', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fe151ab6-aca7-4bd2-b56e-e1bf0eaf5d41'	System	31 Oct 2020 20:29:07
User entered '31 Oct 2020 15:29'	System	31 Oct 2020 20:29:07

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '31 Oct 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 6'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:25', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'None (0)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered 'No (N)'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-01T12:03:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '3bb2d2cd-84ea-4201-b332-a34d524ad4c2'	System	01 Nov 2020 18:03:33
User entered '01 Nov 2020 12:03'	System	01 Nov 2020 18:03:33

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '01 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
Data entry locked.	System	27 Oct 2020 19:12:02
User entered 'Day 7'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:24', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:27', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:31', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:36', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'None (0)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:38', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered 'No (N)'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2020-11-02T12:01:40', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '397a7716-5ab4-44df-b9e4-50b4c39a72ed'	System	02 Nov 2020 18:01:45
User entered '02 Nov 2020 12:01'	System	02 Nov 2020 18:01:45

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '02 Nov 2020 12:00'	System	27 Oct 2020 19:12:02

US3992024

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 12 Aug 2021 13:52:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 02:52:29
User entered '03 Nov 2020 11:59'	System	27 Oct 2020 19:12:02

US3992024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:57:39

US3992024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '5 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:57:39

US3992024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:57:39

US3992024

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:57:39

US3992024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:57:45

US3992024

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	17 Nov 2020 13:57:45

US3992024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:58:32

US3992024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '10 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:58:32

US3992024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:58:32

US3992024

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:58:32

US3992024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	17 Nov 2020 13:58:37

US3992024

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	17 Nov 2020 13:58:37

US3992024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	19 Nov 2020 16:33:44

US3992024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '17 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	19 Nov 2020 16:33:44

US3992024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	19 Nov 2020 16:33:44

US3992024

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	19 Nov 2020 16:33:44

US3992024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	19 Nov 2020 16:33:56

US3992024

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'I'	System	19 Nov 2020 16:33:56

US3992024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 11:59:23

US3992024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '24 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 11:59:23
	(b) (4)	

US3992024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Clinic (Clinic)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 11:59:23

US3992024

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'VISIT3'	System	25 Nov 2020 11:59:23

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '24 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43
	(b) (4)	

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:40'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '24 Nov 2020 15:40'	System	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '36.7' C	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '82'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'bpm'	System	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:01:26
Query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'ncs' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	03 Dec 2020 12:54:32
User opened query 'Per CDM: Per CCG V2.0 page 53, Respiratory Rate: ≥ 17 breaths per minute (breaths/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:27:38
User entered '20'	Karen Cornelius (b) (4) (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'breaths/min'	System	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:01:28
Query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' answered with 'ncs' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	03 Dec 2020 12:54:37
User opened query 'Per CDM: Per CCG V2.0 page 53, SBP ≤ 89 or ≥ 141 mmHg is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you ' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 10:58:00
User entered '141'	Karen Cornelius (b) (4) (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '80'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered 'mmHg'	System	25 Nov 2020 12:03:43

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56

US3992024

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56

US3992024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:57

US3992024

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '24 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:03:57

US3992024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:04:19

US3992024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '24 Nov 2020'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:04:19

US3992024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '15:20'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:04:19

US3992024

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '24 Nov 2020 15:20'	System	25 Nov 2020 12:04:19

US3992024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:04:25

US3992024

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '1'	System	25 Nov 2020 12:04:25

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-04T14:26:39', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a19d9e7a-2019-4d0c-a85f-43db9e855994'	System	04 Jan 2021 20:27:24
User entered 'No (N)'	System	04 Jan 2021 20:27:24

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-01-04T14:27:09', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a19d9e7a-2019-4d0c-a85f-43db9e855994'	System	04 Jan 2021 20:27:24
User entered 'Yes (Y)'	System	04 Jan 2021 20:27:24

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-01-04T14:27:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a19d9e7a-2019-4d0c-a85f-43db9e855994'	System	04 Jan 2021 20:27:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Jan 2021 20:27:24

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-04T14:27:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'a19d9e7a-2019-4d0c-a85f-43db9e855994'	System	04 Jan 2021 20:27:24
User entered '04 Jan 2021 14:27:14'	System	04 Jan 2021 20:27:24

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-10T07:46:03', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8a321c3-d8d9-4783-ae93-2ac8f526b808'	System	10 Jan 2021 13:46:25
User entered 'No (N)'	System	10 Jan 2021 13:46:25

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-01-10T07:46:08', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8a321c3-d8d9-4783-ae93-2ac8f526b808'	System	10 Jan 2021 13:46:25
User entered 'Yes (Y)'	System	10 Jan 2021 13:46:25

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-01-10T07:46:11', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8a321c3-d8d9-4783-ae93-2ac8f526b808'	System	10 Jan 2021 13:46:25
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Jan 2021 13:46:25

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-10T07:46:14', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b8a321c3-d8d9-4783-ae93-2ac8f526b808' User entered '10 Jan 2021 07:46:14'	System	10 Jan 2021 13:46:25
	System	10 Jan 2021 13:46:25

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-17T11:07:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'af2c0dce-52ff-47c2-b864-c16001fc8a24'	System	17 Jan 2021 17:07:21
User entered 'No (N)'	System	17 Jan 2021 17:07:21

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-01-17T11:07:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'af2c0dce-52ff-47c2-b864-c16001fc8a24'	System	17 Jan 2021 17:07:21
User entered 'No (N)'	System	17 Jan 2021 17:07:21

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-17T11:07:17', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'af2c0dce-52ff-47c2-b864-c16001fc8a24'	System	17 Jan 2021 17:07:21
User entered '17 Jan 2021 11:07:17'	System	17 Jan 2021 17:07:21

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:15:40', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'Yes (Y)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:15:46', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'Yes (Y)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:15:52', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:15:56', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'Yes (Y)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '1'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '0'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'Yes (Y)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:17', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-01-22T05:16:21', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'ef0371e5-21aa-45e3-8e0d-afb0dca1c432'	System	22 Jan 2021 11:16:31
User entered '22 Jan 2021 05:16:21'	System	22 Jan 2021 11:16:31

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:06', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'Yes (Y)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:10', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'Yes (Y)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:12', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:15', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'Yes (Y)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '0'	System	01 Feb 2021 12:21:48
	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '1'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '1'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '1'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '1'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '1'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '1'	System	01 Feb 2021 12:21:48
	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:26', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '0'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:29', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:32', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'Yes (Y)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:34', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f'	System	01 Feb 2021 12:21:48
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-01T06:21:37', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '8b67cc98-d62a-42dd-8551-60278ec9595f' User entered '01 Feb 2021 06:21:37'	System	01 Feb 2021 12:21:48
	System	01 Feb 2021 12:21:48

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-05T05:06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c9623bbf-55a3-41a6-979a-cc69ffd35f7a'	System	05 Feb 2021 11:06:11
User entered 'No (N)'	System	05 Feb 2021 11:06:11

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-02-05T05:06:05', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c9623bbf-55a3-41a6-979a-cc69ffd35f7a'	System	05 Feb 2021 11:06:11
User entered 'No (N)'	System	05 Feb 2021 11:06:11

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-05T05:06:08', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c9623bbf-55a3-41a6-979a-cc69ffd35f7a'	System	05 Feb 2021 11:06:11
User entered '05 Feb 2021 05:06:08'	System	05 Feb 2021 11:06:11

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-12T06:01:23', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fa58eaad-eb30-4865-a021-acab80aad021'	System	12 Feb 2021 12:01:37
User entered 'No (N)'	System	12 Feb 2021 12:01:37

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-02-12T06:01:28', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fa58eaad-eb30-4865-a021-acab80aad021'	System	12 Feb 2021 12:01:37
User entered 'No (N)'	System	12 Feb 2021 12:01:37

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-12T06:01:30', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'fa58eaad-eb30-4865-a021-acab80aad021' User entered '12 Feb 2021 06:01:30'	System	12 Feb 2021 12:01:37
	System	12 Feb 2021 12:01:37

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-02-26T17:55:11-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c4b9b0ee-00db-48b6-a6e0-043cc746d668'	System	26 Feb 2021 23:55:20
User entered 'No (N)'	System	26 Feb 2021 23:55:20

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-02-26T17:55:12-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c4b9b0ee-00db-48b6-a6e0-043cc746d668'	System	26 Feb 2021 23:55:20
User entered 'No (N)'	System	26 Feb 2021 23:55:20

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-02-26T17:55:15-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c4b9b0ee-00db-48b6-a6e0-043cc746d668'	System	26 Feb 2021 23:55:20
User entered '26 Feb 2021 17:55:15'	System	26 Feb 2021 23:55:20

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-03-05T06:16:16-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '65752233-5cef-4295-bf52-54afb5ddd378'	System	05 Mar 2021 12:16:36
User entered 'No (N)'	System	05 Mar 2021 12:16:36

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-03-05T06:16:27-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '65752233-5cef-4295-bf52-54afb5ddd378'	System	05 Mar 2021 12:16:36
User entered 'No (N)'	System	05 Mar 2021 12:16:36

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-03-05T06:16:30-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '65752233-5cef-4295-bf52-54afb5ddd378'	System	05 Mar 2021 12:16:36
User entered '05 Mar 2021 06:16:30'	System	05 Mar 2021 12:16:36

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-03-19T05:59:11-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa833e69-e90d-4009-b0de-d31e17344773'	System	19 Mar 2021 10:59:42
User entered 'Yes (Y)'	System	19 Mar 2021 10:59:42

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-03-19T05:59:18-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa833e69-e90d-4009-b0de-d31e17344773'	System	19 Mar 2021 10:59:42
User entered 'No (N)'	System	19 Mar 2021 10:59:42

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-03-19T05:59:21-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa833e69-e90d-4009-b0de-d31e17344773'	System	19 Mar 2021 10:59:42
User entered 'No (N)'	System	19 Mar 2021 10:59:42

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-03-19T05:59:35-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa833e69-e90d-4009-b0de-d31e17344773'	System	19 Mar 2021 10:59:42
User entered 'No (N)'	System	19 Mar 2021 10:59:42

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-03-19T05:59:38-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'aa833e69-e90d-4009-b0de-d31e17344773'	System	19 Mar 2021 10:59:42
User entered '19 Mar 2021 05:59:38'	System	19 Mar 2021 10:59:42

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-03-26T01:52:25-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1737d4a8-9ad1-46b3-9423-ac92faac3d6b'	System	26 Mar 2021 06:52:46
User entered 'No (N)'	System	26 Mar 2021 06:52:46

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-03-26T01:52:29-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1737d4a8-9ad1-46b3-9423-ac92faac3d6b' User entered 'Yes (Y)'	System	26 Mar 2021 06:52:46
	System	26 Mar 2021 06:52:46

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-03-26T01:52:31-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1737d4a8-9ad1-46b3-9423-ac92faac3d6b'	System	26 Mar 2021 06:52:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Mar 2021 06:52:46

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-03-26T01:52:34-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '1737d4a8-9ad1-46b3-9423-ac92faac3d6b' User entered '26 Mar 2021 01:52:34'	System	26 Mar 2021 06:52:46
	System	26 Mar 2021 06:52:46

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-04-06T11:49:20-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c971e152-8a76-4104-b0ba-65098ee4ee4a'	System	06 Apr 2021 16:49:38
User entered 'No (N)'	System	06 Apr 2021 16:49:38

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-04-06T11:49:22-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c971e152-8a76-4104-b0ba-65098ee4ee4a'	System	06 Apr 2021 16:49:38
User entered 'No (N)'	System	06 Apr 2021 16:49:38

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-04-06T11:49:29-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'c971e152-8a76-4104-b0ba-65098ee4ee4a'	System	06 Apr 2021 16:49:38
User entered '06 Apr 2021 11:49:29'	System	06 Apr 2021 16:49:38

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-04-09T04:48:12-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b347a23a-78ba-474e-af4f-bcdb3a4603be' User entered 'No (N)'	System	09 Apr 2021 09:48:39
	System	09 Apr 2021 09:48:39

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-04-09T04:48:18-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b347a23a-78ba-474e-af4f-bcdb3a4603be'	System	09 Apr 2021 09:48:39
User entered 'Yes (Y)'	System	09 Apr 2021 09:48:39

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Please 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 (74b1c1e5fc28a99e)', Time: '2021-04-09T04:48:22-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b347a23a-78ba-474e-af4f-bcdb3a4603be'	System	09 Apr 2021 09:48:39
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Apr 2021 09:48:39

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-04-09T04:48:27-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: 'b347a23a-78ba-474e-af4f-bcdb3a4603be' User entered '09 Apr 2021 04:48:27'	System	09 Apr 2021 09:48:39
	System	09 Apr 2021 09:48:39

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-04-16T01:45:03-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '106c63c9-6012-432f-8c23-83196393810b'	System	16 Apr 2021 06:45:27
User entered 'No (N)'	System	16 Apr 2021 06:45:27

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-04-16T01:45:08-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '106c63c9-6012-432f-8c23-83196393810b'	System	16 Apr 2021 06:45:27
User entered 'Yes (Y)'	System	16 Apr 2021 06:45:27

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Please 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 (74b1c1e5fc28a99e)', Time: '2021-04-16T01:45:11-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '106c63c9-6012-432f-8c23-83196393810b'	System	16 Apr 2021 06:45:27
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Apr 2021 06:45:27

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-04-16T01:45:15-05:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '106c63c9-6012-432f-8c23-83196393810b'	System	16 Apr 2021 06:45:27
User entered '16 Apr 2021 01:45:15'	System	16 Apr 2021 06:45:27

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-04-25T19:46:57-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6f8973e5-97c2-41c4-bcf5-5144fc01745b'	System	26 Apr 2021 02:47:17
User entered 'No (N)'	System	26 Apr 2021 02:47:17

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-04-25T19:47:00-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6f8973e5-97c2-41c4-bcf5-5144fc01745b'	System	26 Apr 2021 02:47:17
User entered 'Yes (Y)'	System	26 Apr 2021 02:47:17

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Please 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 (74b1c1e5fc28a99e)', Time: '2021-04-25T19:47:02-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6f8973e5-97c2-41c4-bcf5-5144fc01745b'	System	26 Apr 2021 02:47:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Apr 2021 02:47:17

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-04-25T19:47:05-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '6f8973e5-97c2-41c4-bcf5-5144fc01745b'	System	26 Apr 2021 02:47:17
User entered '25 Apr 2021 19:47:05'	System	26 Apr 2021 02:47:17

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[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 (74b1c1e5fc28a99e)', Time: '2021-04-30T09:23:09-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '759dd770-25ff-4eeb-b267-9fc6a23c2f4c'	System	30 Apr 2021 16:32:19
User entered 'No (N)'	System	30 Apr 2021 16:32:19

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

Have you been exposed to someone with 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 (74b1c1e5fc28a99e)', Time: '2021-04-30T09:23:11-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '759dd770-25ff-4eeb-b267-9fc6a23c2f4c'	System	30 Apr 2021 16:32:19
User entered 'No (N)'	System	30 Apr 2021 16:32:19

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-04-30T09:23:15-07:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '759dd770-25ff-4eeb-b267-9fc6a23c2f4c'	System	30 Apr 2021 16:32:19
User entered '30 Apr 2021 09:23:15'	System	30 Apr 2021 16:32:19

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '18 Nov 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '22 Nov 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '25 Nov 2022 00:01'	System	20 Nov 2020 10:31:13

US3992024

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:52:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 10:31:13
Amendment Manager: User entered '29 Nov 2022 23:59'	System	20 Nov 2020 10:31:13

US3992024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:52:16

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)	26 Apr 2021 05:30:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-03-05T06:15:54-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '30287e06-1d84-4359-b0c5-af9f4d7e91ff'	System	05 Mar 2021 12:16:02
User entered 'No (N)'	System	05 Mar 2021 12:16:02

US3992024

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:52:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:30:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (74b1c1e5fc28a99e)', Time: '2021-03-05T06:15:58-06:00', User OID: 'PatientReportedOutcome (US3992024)', ODM File OID: '30287e06-1d84-4359-b0c5-af9f4d7e91ff'	System	05 Mar 2021 12:16:02
User entered '05 Mar 2021 06:15:58'	System	05 Mar 2021 12:16:02

US3992024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	03 Jan 2021 13:05:48

US3992024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '22 Dec 2020'	(b) (4) Karen Cornelius (b) (4)	03 Jan 2021 13:05:48

US3992024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	03 Jan 2021 13:05:48

US3992024

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	03 Jan 2021 13:05:48

US3992024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	03 Jan 2021 13:05:54

US3992024

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:19:56
User entered '1'	System	03 Jan 2021 13:05:54

US3992024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	03 Feb 2021 13:05:18

US3992024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '25 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	03 Feb 2021 13:05:18

US3992024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	03 Feb 2021 13:05:18

US3992024

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	03 Feb 2021 13:05:18

US3992024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	03 Feb 2021 13:05:34

US3992024

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User entered 'I'	System	03 Feb 2021 13:05:34

US3992024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Feb 2021 16:17:30

US3992024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	24 Feb 2021 16:17:30

US3992024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Karen Cornelius (b) (4)	24 Feb 2021 16:17:30

US3992024

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered empty.	(b) (4) Karen Cornelius (b) (4)	24 Feb 2021 16:17:30

US3992024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Feb 2021 16:17:18

US3992024

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User entered '1'	System	24 Feb 2021 16:17:18

US3992024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	26 Mar 2021 20:57:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:10:58

US3992024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	26 Mar 2021 20:57:56
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:10:58

US3992024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	26 Mar 2021 20:57:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:10:58

US3992024

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:52:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	26 Mar 2021 20:57:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:10:58

US3992024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User signature succeeded.	Kathleen Mullane (b) (4)	26 Mar 2021 20:57:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Mar 2021 20:11:31

US3992024

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 06:57:45
User entered 'I'	System	26 Mar 2021 20:11:31

US3992024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:56:41

US3992024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:56:41

US3992024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:56:41

US3992024

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	23 Apr 2021 17:56:41

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '10:55'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User entered '22 Apr 2021 10:55'	System	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '36.4' C	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '58'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '14'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '142'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '89'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	23 Apr 2021 17:58:13

US3992024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:21

US3992024

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:21

US3992024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:46

US3992024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '22 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:46

US3992024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered '11:08'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:46

US3992024

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User entered '22 Apr 2021 11:08'	System	23 Apr 2021 18:01:46

US3992024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Apr 2021 17:32:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:01:51

US3992024

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:52:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 18:01:51

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:52:16

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:06:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:15:44
User entered '21 Jan 2021'	Karen Cornelius (b) (4)	22 Jan 2021 13:00:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:52:16

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:06:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:15:44
User entered '10:45'	Karen Cornelius (b) (4)	22 Jan 2021 13:00:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:52:16

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:06:52
User entered '21 Jan 2021 10:45'	System	22 Jan 2021 13:00:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:52:16

Type of Contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:06:52
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:00:48
User closed query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).	(b) (4), (b) (6)	03 Mar 2021 18:00:42
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
Query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' answered with 'changed per query ' (Site from CRA).	Karen Cornelius (b) (4)	21 Feb 2021 16:11:03
DataPoint Un-verified.	Karen Cornelius (b) (4)	21 Feb 2021 16:10:48
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	21 Feb 2021 16:10:48
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:15:44
User opened query ' Per ETRTR: Please consider to update Type of contact to Clinic Visit - Unscheduled /Safety Call as applicable.' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 16:48:09
User entered 'Convalescent Tele-visit (Convalescent Tele-visit)'	Karen Cornelius (b) (4)	22 Jan 2021 13:00:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID-19 Contact

Generated On: 12 Aug 2021 13:52:16

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:06:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:15:44
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 13:00:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 1 (Day 1)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '19 Jan 2021' reason for change: Data Entry Error	Karen Cornelius (b) (4)	27 Jan 2021 12:22:48
User entered '21 Jan 2021'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered missing code ND - Not Done; reason for change New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:22:48
User entered '87' reason for change: New Information	Karen Cornelius (b) (4)	22 Jan 2021 13:06:19
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	22 Jan 2021 13:06:19
User entered empty.	System	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered missing code ND - Not Done; reason for change New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:22:48
User entered '98.0' F reason for change: New Information	Karen Cornelius (b) (4)	22 Jan 2021 13:06:19
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:22:48
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:22:48
User entered 'Mild (Mild)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	27 Jan 2021 12:22:48
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (1)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	22 Jan 2021 13:03:33

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 2 (Day 2)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '20 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:24:31
User entered '22 Jan 2021'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered missing code ND - Not Done; reason for change New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:24:31
User entered '99'	(b) (4) Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Karen Cornelius (b) (4)	27 Jan 2021 12:24:31
User entered '98.4' F	(b) (4) Karen Cornelius (b) (4)	24 Jan 2021 16:44:28
	(b) (4)	

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:24:31
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:24:31
User entered 'Moderate (Moderate)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:44:28

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	27 Jan 2021 12:24:31
User entered 'Moderate (Moderate)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:44:28

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (2)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	24 Jan 2021 16:44:28

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 3 (Day 3)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '21 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:26:50
User entered '24 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '87' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:26:50
User entered '99'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered missing code ND - Not Done; reason for change New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:26:50
User entered '98.4' F	(b) (4) Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:26:50
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:26:50
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:50
User entered 'None (None)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	27 Jan 2021 12:26:50
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (3)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:11:12

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 4 (Day 4)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '22 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered '24 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '99' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered '100'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '98.4' F reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered '97.6' F	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered 'Mild (Mild)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered 'Mild (Mild)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:34:08
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (4)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:13:57

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 5 (Day 5)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '23 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:35:57
User entered '25 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '99'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '98.4' F reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:35:57
User entered '98.2' F	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)' reason for change: New Information	Karen Cornelius (b) (4)	27 Jan 2021 12:35:57
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (5)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:16:14

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 6 (Day 6)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '24 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '100'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:37:10

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '97.6' F	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (6)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:37:10

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 7 (Day 7)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '25 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '99'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '98.2' F	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Not Done (Not Done)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (7)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:38:21

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 8 (Day 8)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '26 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '99'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '98.6' F	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	28 Jan 2021 12:16:01
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (8)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	27 Jan 2021 12:40:24

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 9 (Day 9)'	(b) (4) Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Per protocol they need to do 14 days of telemedicine calls or until symptoms resolve whichever is longer. AE indicates still ongoing so please add subsequent dates or if stopped, please enter a stop date on the AE page thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 04:20:18
Query 'Per protocol they need to do 14 days of telemedicine calls or until symptoms resolve whichever is longer. AE indicates still ongoing so please add subsequent dates or if stopped, please enter a stop date on the AE page thanks' answered with 'data updated' (Site from CRA).	Karen Cornelius (b) (4) (b) (4)	08 Feb 2021 16:59:04
User opened query 'Per protocol they need to do 14 days of telemedicine calls or until symptoms resolve whichever is longer. AE indicates still ongoing so please add subsequent dates or if stopped, please enter a stop date on the AE page thanks' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 16:35:01
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '27 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '99'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered '98.3' F	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Moderate (Moderate)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Not Done (Not Done)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (9)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 16:34:03
User entered 'None (None)'	Karen Cornelius (b) (4)	28 Jan 2021 12:20:55

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 10 (Day 10)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '28 Jan 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '99'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.2' F	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (10)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:00:31

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 11 (Day 11)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '29 Jan 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.4' F	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (11)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:01:50

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 12 (Day 12)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '30 Jan 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '99'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.2' F	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (12)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:02:40

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 13 (Day 13)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '31 Jan 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '99'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.1' F	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'Mild (Mild)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (13)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:03:42

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 14 (Day 14)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '01 Feb 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '99'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.2' F	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (14)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:05:46

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 15 (Day 15)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '02 Feb 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '100'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.2' F	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (15)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:06:43

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Day 16 (Day 16)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '03 Feb 2021'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '0'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '99'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User entered '%'	System	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered '98.4' F	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Symptom Log (16)

Generated On: 12 Aug 2021 13:52:16

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 05:07:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:31
User entered 'None (None)'	Karen Cornelius (b) (4)	08 Feb 2021 17:12:36

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered '21 Jan 2021'	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:16:43
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	25 Jan 2021 12:28:53
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'AE added' (Site from System).	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:37:29
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 13:08:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 13:08:08
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	22 Jan 2021 13:08:08
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:08:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 13:07:04
User entered empty.	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:07:04

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered '21 Jan 2021'	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:07:04

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

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)	01 May 2021 13:52:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 23:45:09
User closed query 'Per CDM, per sponsor review: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present. Please review and reconcile. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 12:22:08
User signature succeeded.	Kathleen Mullane (b) (4)	09 Apr 2021 15:40:25
Query 'Per CDM, per sponsor review: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present. Please review and reconcile. Else clarify. ' answered with 'data updated; test was also performed at hospital lab' (Site from DM).	Karen Cornelius (b) (4)	09 Apr 2021 11:28:44
DataPoint Un-verified.	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
Signature has been broken.	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User entered 'No (N)' reason for change: Per Query Resolution	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User opened query 'Per CDM, per sponsor review: Was this diagnostic test performed at a lab other than the Study Central Lab? Is marked YES but Preclarus positive central lab result present. Please review and reconcile. Else clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 10:38:10
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 13:08:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Jan 2021 13:08:08
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4)	22 Jan 2021 13:08:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Jan 2021 13:07:04
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 23:45:11
User signature succeeded.	Kathleen Mullane (b) (4)	09 Apr 2021 15:40:25
DataPoint Un-verified.	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User signature succeeded.	(b) (4)	
	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered 'University of Chicago' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 13:08:08
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04
	(b) (4)	

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 23:45:12
User signature succeeded.	Kathleen Mullane (b) (4)	09 Apr 2021 15:40:25
DataPoint Un-verified.	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Karen Cornelius (b) (4)	09 Apr 2021 11:27:56
User signature succeeded.	(b) (4)	
	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 16:16:43
User entered 'Yes (Y)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 13:08:08
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 13:07:04
	(b) (4)	

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Folder: Covid-19 Assessment 21 Jan 2021

Form: COVID Diagnostic Test

Generated On: 12 Aug 2021 13:52:16

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:52:51
User entered 'I'	System	22 Jan 2021 13:08:08

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

Did the subject have Respiratory Rates ≥ 30 per Minute?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:03:21
User closed query 'Per CDM: Per sponsor review, Symptom Log Day 3 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:49:14
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
Query 'Per CDM: Per sponsor review, Symptom Log Day 3 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' answered with 'data corrected' (Site from DM).	Karen Cornelius (b) (4)	25 Feb 2021 14:28:29
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 14:28:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 14:28:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	25 Feb 2021 14:28:01
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 14:25:04
DataPoint Un-verified.	Karen Cornelius (b) (4)	25 Feb 2021 14:25:04
User entered empty; reason for change Data Entry Error	Karen Cornelius (b) (4)	25 Feb 2021 14:25:04
User opened query 'Per CDM: Per sponsor review, Symptom Log Day 3 reports SpO2 < 93%. However, Did the Subject have Oxygen Saturation of SpO2 < 93%? is recorded as No. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 15:06:50
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:03:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Un-verified.	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
User entered '21 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13
	(b) (4)	

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Folder: Covid-19 Assessment 21 Jan 2021

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:03:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Un-verified.	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
User entered '22 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13
	(b) (4)	

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[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:03:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Un-verified.	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
User entered '87' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	25 Feb 2021 14:29:24
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13
	(b) (4)	

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Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[High-Flow Oxygen?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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[ECMO?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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[Evidence of Shock Requires](#)

[Vasopressors](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
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[Acute Renal Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
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[Hepatic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

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User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Neurologic Dysfunction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Radiographical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Date of Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Admission to an intensive care unit due to SARS-CoV-2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Covid-19 Severity Assessment

Generated On: 12 Aug 2021 13:52:16

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:33:24
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 13:09:13

US3992024

Folder: Covid-19 Assessment 21 Jan 2021

Form: Generate Next COVID-19 Assessment

Generated On: 12 Aug 2021 13:52:16

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:53:12
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:03:38
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	05 Feb 2021 14:58:10

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '23 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '25 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '27 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '29 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '03 Feb 2021'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '10 Feb 2021'	(b) (4) Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:52:16

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:52:16

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User closed query 'PER CDM: Re-Query: As per previous response it was reported as 'data will be entered once obtained'. However, request you please keep this query open until site get results and data recorded as appropriate. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Kathleen Mullane (b) (4)	01 Mar 2021 13:35:17 25 Feb 2021 22:23:19
Query 'PER CDM: Re-Query: As per previous response it was reported as 'data will be entered once obtained'. However, request you please keep this query open until site get results and data recorded as appropriate. Thank you.' answered with 'data updated' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	25 Feb 2021 16:07:59
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4) (b) (4)	25 Feb 2021 16:07:42
User opened query 'PER CDM: Re-Query: As per previous response it was reported as 'data will be entered once obtained'. However, request you please keep this query open until site get results and data recorded as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 12:09:02
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Feb 2021 12:08:21
Query 'Data is required. Please complete.' answered with 'data will be entered once obtained' (Site from System).	Karen Cornelius (b) (4) (b) (4)	13 Feb 2021 12:03:10
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Feb 2021 12:02:27
User entered empty; reason for change Data Entry Error	Karen Cornelius (b) (4) (b) (4)	13 Feb 2021 12:02:27
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:04:24
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19FEB2021 is reported under Convalescence Visit Day 28 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)	26 Feb 2021 10:09:29
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19FEB2021 is reported under Convalescence Visit Day 28 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.' answered with 'data updated' (Site from DM).	Karen Cornelius (b) (4)	25 Feb 2021 16:08:07
User entered '19 Feb 2021' reason for change: New Information	(b) (4)	25 Feb 2021 16:07:42
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19FEB2021 is reported under Convalescence Visit Day 28 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)	25 Feb 2021 10:50:45
User entered empty.	Karen Cornelius (b) (4)	12 Feb 2021 15:38:07

US3992024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:01:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Saliva collection data is missing, if collected, please enter data, thanks' (Site from CRA).	(b) (4) (b) (4), (b) (6)	25 Feb 2021 04:19:45
Query 'Saliva collection data is missing, if collected, please enter data, thanks' answered with 'Data updated' (Site from CRA).	Karen Cornelius (b) (4) (b) (4)	12 Feb 2021 15:40:02
User opened query 'Saliva collection data is missing, if collected, please enter data, thanks' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 16:36:59
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:31:54
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:01:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:31:54
User entered '21 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[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 07:01:52
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:31:54
User entered 'Clinic (Clinic)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:01:52
User entered 'SICKD1'	System	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '21 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User closed query 'Data is required. Please provide.' (Site from System).	System	26 Jan 2021 16:06:01
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	26 Jan 2021 16:06:01
User entered '10:45' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	26 Jan 2021 16:06:01
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Jan 2021 13:12:52
User entered empty.	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User entered '21 Jan 2021 10:45'	System	26 Jan 2021 16:06:01
User entered empty.	System	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '69' in reason for change: New Information	Karen Cornelius (b) (4)	26 Jan 2021 16:07:50
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 13:12:52
DataPoint set to visible.	(b) (4) System	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '167' lb reason for change: Data Entry Error	Karen Cornelius (b) (4)	26 Jan 2021 16:07:50
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 13:12:52
DataPoint set to visible.	(b) (4) System	22 Jan 2021 13:10:06

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '98.0' F	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered 'Other (Other)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered 'unknown'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '65'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User entered 'bpm'	System	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '14'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User entered 'breaths/min'	System	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '132'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User entered 'mmHg'	System	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:12
User entered '68'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00
User entered 'mmHg'	System	22 Jan 2021 13:12:52

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00

US3992024

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:00

US3992024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:05
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:04
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:13:04

US3992024

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:05
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:04
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Jan 2021 13:13:17
User entered '21 Jan 2021' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:13:17
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Jan 2021 13:13:04
User entered '21 2021' (non-conformant).	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:13:04

US3992024

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:52:16

[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 07:02:12
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:10
User entered 'Yes (Y)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:13:44

US3992024

Folder: Illness Visit Day 1 (1)

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

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:12
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:32:10
User entered '21 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 13:13:44

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:36
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:39
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:36
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:39
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '19 Feb 2021'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[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 07:02:36
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:39
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Clinic (Clinic)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:36
User entered 'SICKD28'	System	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '19 Feb 2021'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '08:29'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
User entered '19 Feb 2021 08:29'	System	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	21 Feb 2021 13:30:53
DataPoint set to visible.	(b) (4) System	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered missing code ND - Not Done.	(b) (4) Karen Cornelius (b) (4)	21 Feb 2021 13:30:53
DataPoint set to visible.	(b) (4) System	21 Feb 2021 13:29:00

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 13:38:34
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 16:08:10
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Feb 2021 13:30:53
User entered '35.9' C	Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Other (Other)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'unknown'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User closed query 'Per CDM: Per CCG V2.0 page 53, PULSE ≤ 54 or ≥ 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:50:30
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
Query 'Per CDM: Per CCG V2.0 page 53, PULSE ≤ 54 or ≥ 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' answered with 'ncs' (Site from DM).	(b) (4) Karen Cornelius (b) (4)	25 Feb 2021 15:59:23
User opened query 'Per CDM: Per CCG V2.0 page 53, PULSE ≤ 54 or ≥ 101 beats per minute (beats/min) is considered as clinically abnormal. Please confirm if the out of range is CS/NCS. If CS then report as AE and update as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 18:42:45
User entered '52'	Karen Cornelius (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
User entered 'bpm'	System	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '16'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
User entered 'breaths/min'	System	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '128'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
User entered 'mmHg'	System	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:57:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '86'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53
User entered 'mmHg'	System	21 Feb 2021 13:30:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:52:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:02:53

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:03:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:58:03
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:31:03

US3992024

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:52:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:03:00
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:58:03
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '19 Feb 2021'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:31:03

US3992024

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:52:16

[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 07:03:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:58:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:32:03

US3992024

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 12 Aug 2021 13:52:16

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:03:11
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 18:58:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
User entered '19 Feb 2021'	(b) (4) Karen Cornelius (b) (4) (b) (4)	21 Feb 2021 13:32:03

US3992024

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

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	05 Jan 2021 12:00:03
	(b) (4)	

US3992024

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

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '04 Jan 2021'	Karen Cornelius (b) (4)	05 Jan 2021 12:00:03
	(b) (4)	

US3992024

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

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[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 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Clinic (Clinic)'	Karen Cornelius (b) (4)	05 Jan 2021 12:00:03
	(b) (4)	

US3992024

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

Form: Visit Date

Generated On: 12 Aug 2021 13:52:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 12:00:03

US3992024

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	15 Apr 2021 04:47:20
User closed query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 16:01:07
Query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5. ' answered with 'data entry error' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	08 Apr 2021 17:40:09
Signature has been broken.	Karen Cornelius (b) (4) (b) (4)	08 Apr 2021 17:39:38
User entered '04 Jan 2021' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	08 Apr 2021 17:39:38
User opened query 'Per sponsor review, This field relates to Amendment 6. The Amendment 6 consent form was not available until 29DEC2020. Please review and update field to the date the subject signed the Amendment 6 or later consent form. If the subject was unblinded and discontinued under Amendment 5, please tick the box below indicating that the consent field is N/A and the subject was unblinded and discontinued under Amendment 5. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 17:54:01
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:23:19

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 Jan 2020'	Karen Cornelius (b) (4) (b) (4)	05 Jan 2021 12:01:23

US3992024

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:01:21
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:55:01

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	15 Mar 2021 20:01:21
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 19:55:01

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	15 Apr 2021 04:47:20
	(b) (4)	
User closed query 'Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 16:01:12
Query 'Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile. ' answered with 'data entry error' (Site from DM).	Karen Cornelius (b) (4)	08 Apr 2021 17:40:32
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	08 Apr 2021 17:38:10
User entered '04 Jan 2021' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per IRT, subject was unblinded on 04JAN2021. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 09:34:06
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '04 Jan 2020'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'mRNA-1273 (mRNA-1273)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 15:30:38
User entered 'mRNA-1273 (mRNA-1273)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 15:30:38
User entered 'mRNA-1273 (mRNA-1273)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:23
	(b) (4)	

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	05 Jan 2021 12:01:23

US3992024

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

Form: Unblinding

Generated On: 12 Aug 2021 13:52:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered empty.	System	05 Jan 2021 12:01:23

US3992024

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:57
	(b) (4)	

US3992024

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	11 Jan 2021 15:17:44
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		11 Jan 2021 15:17:44
User closed query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).	System	11 Jan 2021 15:17:44
User closed query 'The Collection Date is prior to the System Screening Visit Date. Please review and reconcile.' (Site from System).		11 Jan 2021 15:17:44
User entered '04 Jan 2021' reason for change: Data Entry Error	Karen Cornelius (b) (4)	11 Jan 2021 15:17:44
	(b) (4)	
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	05 Jan 2021 12:01:57
User opened query 'The Collection Date is before the Date of Informed Consent. Please review and reconcile.' (Site from System).		05 Jan 2021 12:01:57
User opened query 'The Collection Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	05 Jan 2021 12:01:57
User entered '04 Jan 2020'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:57
	(b) (4)	

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

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '14:20'	Karen Cornelius (b) (4)	05 Jan 2021 12:01:57
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:52:16

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '04 Jan 2021 14:20'	System	11 Jan 2021 15:17:44
User entered '04 Jan 2020 14:20'	System	05 Jan 2021 12:01:57

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:52:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	05 Jan 2021 12:02:17
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:52:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '04 Jan 2021'	Karen Cornelius (b) (4)	05 Jan 2021 12:02:17
	(b) (4)	

US3992024

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:52:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '14:22'	Karen Cornelius (b) (4)	05 Jan 2021 12:02:17
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:52:16

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:17:16
User entered '04 Jan 2021 14:22'	System	05 Jan 2021 12:02:17

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 12 Aug 2021 13:52:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:32
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:34:59
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 15:37:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 20:42:51
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'USA-US219-2021-mRNA-1273-P301000003'	System	25 Jan 2021 18:27:26
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 18:27:26

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 15:41:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Jan 2021 15:41:01
Data point term sent to Coder	System	22 Jan 2021 15:40:27
User entered 'COVID 19'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'No (N)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	05 Apr 2021 17:27:17
User closed query 'PV Query: Please clarify event onset date; subject reports symptoms via symptom log on 19 Jan 2021, but event onset date is listed as 21 Jan 2021. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 20:19:54
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:05:13
Query 'PV Query: Please clarify event onset date; subject reports symptoms via symptom log on 19 Jan 2021, but event onset date is listed as 21 Jan 2021. ' answered with 'updated' (Site from Safety).	Jill Stetkevych (b) (4) (b) (4)	01 Apr 2021 15:24:05
DataPoint Un-verified.	Jill Stetkevych (b) (4) (b) (4)	01 Apr 2021 15:23:36
Signature has been broken.	Jill Stetkevych (b) (4) (b) (4)	01 Apr 2021 15:23:36
User entered '19 Jan 2021' reason for change: Data Entry Error	Jill Stetkevych (b) (4) (b) (4)	01 Apr 2021 15:23:36
User opened query 'PV Query: Please clarify event onset date; subject reports symptoms via symptom log on 19 Jan 2021, but event onset date is listed as 21 Jan 2021. ' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 13:14:06
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '21 Jan 2021'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User closed query 'Per MM, please provide the end date.	(b) (4), (b) (6)	18 Feb 2021 14:14:49
' (Site from DM).		
Query 'Per MM, please provide the end date.	Karen Cornelius (b) (4)	17 Feb 2021 17:24:47
' answered with 'data updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Karen Cornelius (b) (4)	17 Feb 2021 17:24:35
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Karen Cornelius (b) (4)	17 Feb 2021 17:24:35
	(b) (4)	
User opened query 'Per MM, please provide the end date.	(b) (4), (b) (6)	15 Feb 2021 14:25:26
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify event end date; symptom log reports no symptoms beginning 01 Feb 2021, but event end date is listed as 04 Feb 2021. ' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 20:20:04
Query 'PV Query: Please clarify event end date; symptom log reports no symptoms beginning 01 Feb 2021, but event end date is listed as 04 Feb 2021. ' answered with 'correct as entered per patient's medical record' (Site from Safety).	Jill Stetkevych (b) (4)	01 Apr 2021 15:26:01
User opened query 'PV Query: Please clarify event end date; symptom log reports no symptoms beginning 01 Feb 2021, but event end date is listed as 04 Feb 2021. ' (Site from Safety).	(b) (4)	01 Apr 2021 13:14:18
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User closed query 'Please confirm if ongoing, if not, please enter stop date' (Site from CRA).	(b) (4)	25 Feb 2021 04:20:59
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
Query 'Please confirm if ongoing, if not, please enter stop date' answered with 'data updated' (Site from CRA).	Karen Cornelius (b) (4)	17 Feb 2021 17:24:54
DataPoint Un-verified.	(b) (4)	17 Feb 2021 17:24:35
User entered '04 Feb 2021' reason for change: Data Entry Error	Karen Cornelius (b) (4)	17 Feb 2021 17:24:35
User opened query 'Please confirm if ongoing, if not, please enter stop date' (Site from CRA).	(b) (4)	08 Feb 2021 16:33:39
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Per safety: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available ' (Site from DM).	(b) (4), (b) (6)	27 Apr 2021 14:59:48
Query 'Per safety: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available ' answered with 'end date has been provided with recovered' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	26 Apr 2021 14:27:45
User opened query 'Per safety: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 15:58:17
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:25:33
User opened query 'Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from Safety).	(b) (4), (b) (6)	12 Feb 2021 15:25:51
User entered empty.	System	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Not Related (NOT RELATED)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Not Related (NOT RELATED)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:05:13
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:40:41
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 14:49:14
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jill Stetkevych (b) (4) (b) (4)	03 Mar 2021 17:00:57
DataPoint Un-verified.	Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
Signature has been broken.	(b) (4) Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
User entered '0' reason for change: Data Entry Error	(b) (4) Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Feb 2021 00:25:58
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '1'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:05:13
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:40:41
DataPoint Un-verified.	(b) (4)	
	Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
Signature has been broken.	(b) (4)	
	Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Jill Stetkevych (b) (4)	03 Mar 2021 17:00:47
User signature succeeded.	(b) (4)	
	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'		
	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Kathleen Mullane (b) (4)	04 Mar 2021 20:42:38 25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
Query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'data updated' (Site from Safety). DataPoint Un-verified.	Karen Cornelius (b) (4) Karen Cornelius (b) (4)	17 Feb 2021 17:25:03 17 Feb 2021 17:24:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Karen Cornelius (b) (4)	17 Feb 2021 17:24:35
User opened query 'Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Feb 2021 15:25:26 26 Jan 2021 17:35:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:37
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:39:42
	(b) (4)	

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:52:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Jan 2021 15:39:42

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:17:43
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: Pain in extremity, LLT: Calf pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 14:16:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Jan 2021 14:16:18
Data point term sent to Coder	System	28 Jan 2021 14:15:23
User entered 'Calf pain'	Karen Cornelius (b) (4) (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'No (N)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'No (N)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'No (N)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '27 Jan 2021'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User entered empty.	System	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'No (N)' reason for change: New Information	Karen Cornelius (b) (4)	17 Feb 2021 17:29:23
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '28 Jan 2021' reason for change: New Information	Karen Cornelius (b) (4)	17 Feb 2021 17:29:23
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User entered empty.	System	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'No (N)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'Not Related (NOT RELATED)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'Not Related (NOT RELATED)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'Not Applicable (NOT APPLICABLE)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'I'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered '0'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Karen Cornelius (b) (4)	17 Feb 2021 17:29:23
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
DataPoint Verified.	(b) (4), (b) (6)	19 Feb 2021 16:17:43
User entered empty.	Karen Cornelius (b) (4)	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User entered '0'	System	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21
User entered '0'	System	28 Jan 2021 14:15:15

US3992024

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 12 Aug 2021 13:52:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:57:21

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:52:16

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:34:32
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4)	22 Feb 2021 07:34:07
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 07:34:04
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject reported no intervention required' (Site from DM).	Karen Cornelius (b) (4)	19 Feb 2021 16:34:18
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'subject reported no intervention required' (Site from DM).	Karen Cornelius (b) (4)	19 Feb 2021 16:34:12

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:52:16

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:02:34
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 11:01:58
User entered 'Yes (Y)' reason for change: New Information	Karen Cornelius (b) (4)	04 Oct 2020 15:45:27
User entered 'No (N)'	Jill Stetkevych (b) (4)	28 Sep 2020 20:30:55

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 14:38:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 14:38:23
Data point term sent to Coder	System	04 Oct 2020 15:48:49
User entered 'Duloxetine'	Karen Cornelius (b) (4) (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'anxiety / depression'	Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '60'	Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'mg (mg)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'once daily (QD)'	Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Oral (ORAL)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'un Apr 2019'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)' reason for change: New Information	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:34:21
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'un Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	28 Oct 2020 15:34:21
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	04 Oct 2020 15:48:31
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User entered '1'	System	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User entered '1'	System	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:50
User entered '804 (804)'	System	04 Oct 2020 15:48:31

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 09 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 11:43:29
Query 'Per DM CLR: this Con Med was added/ had dose increased on 09 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Increased dose from 60 to 90 (titrating dose)' (Site from DM).	Karen Cornelius (b) (4)	09 Mar 2021 16:13:32
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 09 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:43:49
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:04:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 18:04:42
Data point term sent to Coder	System	28 Oct 2020 15:35:01
User entered 'duloxetine'	Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'anxiety / depression'	Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '90'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'mg (mg)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'once daily (QD)'	Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Oral (ORAL)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:15:12
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' answered with 'correct as entered, not worsening' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 17:33:47
User entered '09 Oct 2020' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:28:52
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 02:14:04
User entered 'un Oct 2020'	Karen Cornelius (b) (4) (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)' reason for change: New Information	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:27:19
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '30 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 15:27:19
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	28 Oct 2020 15:35:00
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User entered '1'	System	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User entered '1'	System	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:54
User entered '804 (804)'	System	28 Oct 2020 15:35:00

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4)	
	Coder Import (b) (4)	25 Nov 2020 12:07:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Nov 2020 12:07:06
	(b) (4)	
Data point term sent to Coder	System	25 Nov 2020 12:06:15
User entered 'influenza vaccine'	Karen Cornelius (b) (4)	25 Nov 2020 12:05:32
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'influenza prophylaxis'	Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0.5'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'mL (mL)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'once (ONCE)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '17 Nov 2020'	Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '17 Nov 2020'	Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User entered empty.	System	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User entered empty.	System	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:24:57
User entered empty.	System	25 Nov 2020 12:05:32

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Jan 2021 23:15:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:15:06
Data point term sent to Coder	System	22 Jan 2021 15:33:22
User entered 'escitalopram oxalate'	Karen Cornelius (b) (4) (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'anxiety and depresson'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '5'	Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'mg (mg)'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'once daily (QD)'	Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '01 Dec 2020'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '11 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User entered '1'	System	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User entered '1'	System	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:01
User entered '804 (804)'	System	22 Jan 2021 15:32:25

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:23:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 10:23:30
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 12 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:52:18
Query 'Per DM CLR: this Con Med was added/ had dose increased on 12 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no change in grade; correct as entered' (Site from DM).	Jill Stetkevych (b) (4) (b) (4)	30 Mar 2021 20:40:35
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 12 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:44:11
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Jan 2021 23:16:06

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	22 Jan 2021 23:16:06
User: (b) (6) - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	22 Jan 2021 15:33:22
User entered 'escitalopram oxalate'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'anxiety and depression'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '10'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'mg (mg)'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'once daily (QD)'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '12 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	09 Mar 2021 16:34:31
User entered 'No (N)' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	09 Mar 2021 16:34:31
User signature succeeded.	(b) (4)	
	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Yes (Y)'	(b) (4)	
	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
Signature has been broken.	(b) (4)	
	Karen Cornelius (b) (4)	09 Mar 2021 16:34:31
	(b) (4)	
User entered '23 Feb 2021' reason for change: New Information	Karen Cornelius (b) (4)	09 Mar 2021 16:34:31
	(b) (4)	
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	Karen Cornelius (b) (4)	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User entered '1'	System	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User entered '1'	System	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:25:08
User entered '804 (804)'	System	22 Jan 2021 15:33:16

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:03:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Mar 2021 15:03:51
Data point term sent to Coder	System	09 Mar 2021 16:41:50
Coding entries removed.	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:41:05
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 07:30:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 07:30:56
Data point term sent to Coder	System	24 Jan 2021 16:49:09
User entered 'Tylenol pm'	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	(b) (4) Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
User closed query 'Per DM CLR: Please specify the location or type of PAIN. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 11:45:21
Query 'Per DM CLR: Please specify the location or type of PAIN. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' answered with 'updated indication, symptoms all due to Covid-19 and recorded in symptom log' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:42:22
Signature has been broken.	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:41:05
User entered 'COVID 19 (PAIN from HEADACHE, MUSCLE ACHES, BODY ACHES)' reason for change: Per Query Resolution	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:41:05
User opened query 'Per DM CLR: Please specify the location or type of PAIN. Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:44:27
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
User entered 'Covid 19 (pain, headache, muscle aches, body aches)'	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 12:52:35
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'correct as entered per patient's medical record; on-line search indicates the same' (Site from DM).	Jill Stetkevych (b) (4) (b) (4)	30 Mar 2021 20:49:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MCG, etc) instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 13:23:06
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
User entered '2'	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'tablet (TABLET)'	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	24 Jan 2021 16:48:43
User entered 'other (OTHER)' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:48:43
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	24 Jan 2021 16:48:29
User entered 'once daily (QD)'	Karen Cornelius (b) (4) (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Q 6 hrs prn'	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered empty.	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '21 Jan 2021'	(b) (4) Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '0'	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)' reason for change: New Information	(b) (4) Karen Cornelius (b) (4)	09 Feb 2021 11:58:06
User entered 'Yes (Y)'	(b) (4) Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered '31 Jan 2021' reason for change: New Information	(b) (4)	
	Karen Cornelius (b) (4)	09 Feb 2021 11:58:06
User entered empty.	(b) (4)	
	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User entered 'No (N)'	Karen Cornelius (b) (4)	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User entered empty.	System	24 Jan 2021 16:48:43
User entered '1'	System	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User entered empty.	System	24 Jan 2021 16:48:43
User entered '1'	System	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:33:44
User entered empty.	System	24 Jan 2021 16:48:43
User entered '804 (804)'	System	24 Jan 2021 16:48:29

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Jan 2021 13:40:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 13:40:29
Data point term sent to Coder	System	27 Jan 2021 13:38:40
User entered 'apixaban'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:37:58

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'DVT prophylaxis'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Mar 2021 11:45:47
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'corrected' (Site from DM).	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:43:55
Signature has been broken.	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:43:46
User entered '5' reason for change: Data Entry Error	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:43:46
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 02:44:54
User signature succeeded.	Kathleen Mullane (b) (4) (b) (4)	25 Feb 2021 22:20:43
User entered '50'	Karen Cornelius (b) (4) (b) (4)	27 Jan 2021 13:37:58

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'mg (mg)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'twice daily (BID)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered '24 Jan 2021'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:20:43
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	27 Jan 2021 13:37:58
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Jan 2021 13:37:58

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Jan 2021 13:37:58

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Jan 2021 13:37:58

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	31 Mar 2021 11:42:06
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication.	Jill Stetkevych (b) (4) (b) (4)	30 Mar 2021 20:50:46
' answered with 'no change in grade; correct as entered' (Site from DM).		
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new medication. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 23:29:57
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:27:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Mar 2021 11:27:49
Data point term sent to Coder	System	09 Mar 2021 16:36:45
User entered 'Escitalopram oxalate'	Karen Cornelius (b) (4) (b) (4)	09 Mar 2021 16:36:12

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 16:36:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	09 Mar 2021 16:36:22
User entered 'No (N)' reason for change: Data Entry Error	Karen Cornelius (b) (4)	09 Mar 2021 16:36:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Mar 2021 16:36:12
User entered empty.	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'anxiety/depression'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered '15'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'mg (mg)'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'once daily (QD)'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'Oral (ORAL)'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered '24 Feb 2021'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered '0'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'Yes (Y)'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered empty.	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	31 Mar 2021 21:20:03
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	09 Mar 2021 16:36:12
	(b) (4)	

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 16:36:12

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 16:36:12

US3992024

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:52:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 16:36:12

US3992024

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 12 Aug 2021 13:52:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered 'No (N)'	Karen Cornelius (b) (4)	05 Feb 2021 13:30:58
	(b) (4)	

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'USA-US219-2021-MRNA-1273-P301000003'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Kathleen'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Mullane'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '5841 South Maryland Ave MC 5065'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Chicago'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'IL'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '60637'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 20:43:04
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered 'US'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Apr 2021 20:20:18
User entered '2'	System	04 Mar 2021 20:43:26
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '1'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'USA-US219-2021-MRNA-1273-P301000003'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Kathleen'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Mullane'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '5841 South Maryland Ave MC 5065'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Chicago'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'IL'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '60637'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 20:43:04
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered 'US'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Apr 2021 20:20:18
User entered '2'	System	04 Mar 2021 20:43:26
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '1'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:52:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered '25/Jan/2021 18:28'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 12 Aug 2021 13:52:16

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)	04 Mar 2021 20:43:04
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'USA-US219-2021-MRNA-1273-P301000003'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Kathleen'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Mullane'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '5841 South Maryland Ave MC 5065'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Chicago'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'IL'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '60637'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 20:43:04
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered 'US'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Apr 2021 20:20:18
User entered '2'	System	04 Mar 2021 20:43:26
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '1'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:52:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:04:56
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:40:41
User entered '04/Mar/2021 14:43'	(b) (4) System	04 Mar 2021 20:43:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 12 Aug 2021 13:52:16

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)	02 Apr 2021 20:20:22
DataPoint Verified.	(b) (4), (b) (6)	02 Apr 2021 15:04:56
User signature succeeded.	Kathleen Mullane (b) (4)	05 Mar 2021 23:40:41
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 20:43:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'USA-US219-2021-MRNA-1273-P301000003'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'No (N)'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Kathleen'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Mullane'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '5841 South Maryland Ave MC 5065'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'Chicago'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered 'IL'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 17:35:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Jan 2021 18:28:34
User entered '60637'	System	25 Jan 2021 18:27:26

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 20:43:04
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
DataPoint Verified.	(b) (4), (b) (6)	26 Jan 2021 17:35:19
User entered 'US'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 12 Aug 2021 13:52:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Apr 2021 20:20:18
User entered '2'	System	04 Mar 2021 20:43:26
User signature succeeded.	Kathleen Mullane (b) (4)	25 Feb 2021 22:23:19
	(b) (4)	
User entered '1'	System	25 Jan 2021 18:28:41

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:52:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:35:26
User signature succeeded.	Kathleen Mullane (b) (4)	05 Apr 2021 17:27:17
User entered '02/Apr/2021 16:20'	(b) (4) System	02 Apr 2021 20:20:18

US3992024

Folder: SAE USA-US219-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 12 Aug 2021 13:52:16

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)	27 Apr 2021 15:35:26
User signature succeeded.	Kathleen Mullane (b) (4)	05 Apr 2021 17:27:17
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 20:20:22
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 20:20:18