

US3412259 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:35:32

All time stamps listed in this document are displayed in GMT

US3412259

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

[Participant ID](#)

US3412259

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

US3412259

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412259

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Date of Birth (MMM yyyy)	(b) (6) 1953
Age	67
Age Units	YEARS
Age (Derived)	67
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3412259

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Date of Informed Consent (<i>dd MMM yyyy</i>)	17 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3412259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412259

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Were any significant conditions reported?

Yes ☒

No ☐

US3412259

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Condition	HEADACHE MIGRAINE
Start date (dd MMM yyyy)	UN UNK 1963
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 1963
Start Year (derived)	1963
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412259

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Condition	CANCER HISTORY (OVARIAN)
Start date (dd MMM yyyy)	UN UNK 2002
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3412259

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3412259

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	13:28 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:28
Height (xxx.x)	164.5 cm
Weight (xxx.x)	71.5 kg
BMI (xxx.x)	26.42252 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412259

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

US3412259

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Date of assessment (dd MMM yyyy) 17 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2003

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) _____

Date of last menstruation unknown False

US3412259

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186364

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 ☒

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Height	ND - Not Done
Weight	ND - Not Done

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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)	17 AUG 2020
Time of assessment (00:00-23:59)	13:28 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 13:28
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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)	17 AUG 2020
Time of assessment (00:00-23:59)	14:51 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 14:51
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 14:20 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 14:20

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

US3412259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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

Collection date (dd MMM yyyy)	17 AUG 2020
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Collection time (00:00-23:59)	14:00 (24 HR)
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Collection date and time (derived)	17 AUG 2020 14:00
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US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:05	17 AUG 2020 14:05
Nasopharyngeal Swab 2	No		

US3412259

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 14:57

PC Open Date & Time

17 AUG 2020 14:40

PC Close Date & Time

17 AUG 2020 17:10

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

96.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp 17 AUG 2020 20:32

PC Open Date & Time 17 AUG 2020 18:05

PC Close Date & Time 18 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

95.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 20:28

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

19 AUG 2020 20:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 20:29

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 20:16

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 20:34

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °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 AUG 2020 20:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 14:59

PC Open Date & Time

17 AUG 2020 14:40

PC Close Date & Time

17 AUG 2020 17:10

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

17 AUG 2020 20:33

PC Open Date & Time

17 AUG 2020 18:05

PC Close Date & Time

18 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

18 AUG 2020 20:29

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

19 AUG 2020 20:35

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

20 AUG 2020 20:30

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

21 AUG 2020 20:16

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

22 AUG 2020 20:35

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

23 AUG 2020 20:32

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 14:59
PC Open Date & Time	17 AUG 2020 14:40
PC Close Date & Time	17 AUG 2020 17:10

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 20:33
PC Open Date & Time	17 AUG 2020 18:05
PC Close Date & Time	18 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

46 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 20:30
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

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 ☒

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:35
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

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 ☒

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 20:31
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:17
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

54 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:35
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

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 ☒

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EAB) (1725)

56 of 2761

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 20:33
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3412259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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)	21 SEP 2020
Time of assessment (00:00-23:59)	8:48 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 8:48
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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)	21 SEP 2020
Time of assessment (00:00-23:59)	9:58 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 9:58
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 09:25 (24 HR)

Treatment Date and Time (derived) 21 SEP 2020 09:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3412259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was the sample collected? Yes ☒ No ☐

Collection date (dd MMM yyyy) 21 SEP 2020

Collection time (00:00-23:59) 08:55 (24 HR)

Collection date and time (derived) 21 SEP 2020 08:55

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 09:59

PC Open Date & Time

21 SEP 2020 09:45

PC Close Date & Time

21 SEP 2020 12:15

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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 96.5 °F

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

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

PC Time Stamp	21 SEP 2020 20:03
PC Open Date & Time	21 SEP 2020 13:10
PC Close Date & Time	22 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 20:21

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

23 SEP 2020 20:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 20:31

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

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

25 SEP 2020 20:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 19:14

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 20:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

21 SEP 2020 09:59

PC Open Date & Time

21 SEP 2020 09:45

PC Close Date & Time

21 SEP 2020 12:15

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

21 SEP 2020 20:04

PC Open Date & Time

21 SEP 2020 13:10

PC Close Date & Time

22 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 20:21

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 20:02

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 20:31

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 20:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 19:15

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 20:03

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 10:00
PC Open Date & Time	21 SEP 2020 09:45
PC Close Date & Time	21 SEP 2020 12:15

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 20:04
PC Open Date & Time	21 SEP 2020 13:10
PC Close Date & Time	22 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

92 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 20:21
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

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 ☒

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 20:04
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

96 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 20:32
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

98 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:02
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

100 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:15
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

102 of 2761

EAB) (1725)

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 20:03
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3412259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:37

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

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

Collection date (dd MMM yyyy)	19 OCT 2020
-------------------------------	-------------

Collection time (00:00-23:59)	08:15 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 OCT 2020 08:15
------------------------------------	-------------------

US3412259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 05:04:38

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 21:26:20

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 12:03:51

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	31 OCT 2020 17:00:44
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	True
Runny nose	False
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	14 NOV 2020 17:04:27
Patient Cloud Open Date & Time	14 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	118 of 2761

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 NOV 2020 09:10:56

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 DEC 2020 07:05:26

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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	09 DEC 2020 10:16:44
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 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	18 DEC 2020 05:11:37
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 09:41:18

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

30 DEC 2020 05:27:10

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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 JAN 2021 07:57:44
Patient Cloud Open Date & Time	06 JAN 2021 00:01
Patient Cloud Close Date & Time	10 JAN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 JAN 2021 18:07:04

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

21 JAN 2021 06:49:50

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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	29 JAN 2021 01:35:25
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 07:33:38

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 FEB 2021 20:41:40
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 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 FEB 2021 00:38:44
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 08:49:23

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 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	03 MAR 2021 07:57:28
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 07:48:53

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 MAR 2021 16:56:01

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

24 MAR 2021 06:11:49

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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	31 MAR 2021 05:58:06
Patient Cloud Open Date & Time	31 MAR 2021 00:01
Patient Cloud Close Date & Time	04 APR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 06:53:50
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 06:06:15

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 10:00:46

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 06:53:02

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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04 AUG 2021 00:01

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08 AUG 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 OCT 2021 00:01
Patient Cloud Close Date & Time	17 OCT 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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06 FEB 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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09 FEB 2022 00:01

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13 FEB 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

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16 FEB 2022 00:01

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20 FEB 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

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23 FEB 2022 00:01

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27 FEB 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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°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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 MAR 2022 00:01

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06 MAR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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13 MAR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

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16 MAR 2022 00:01

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20 MAR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

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23 MAR 2022 00:01

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27 MAR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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°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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 APR 2022 00:01

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10 APR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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13 APR 2022 00:01

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17 APR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 JUN 2022 00:01
Patient Cloud Close Date & Time	19 JUN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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22 JUN 2022 00:01

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26 JUN 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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06 JUL 2022 00:01

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10 JUL 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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13 JUL 2022 00:01

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17 JUL 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 JUL 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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31 JUL 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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14 AUG 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 AUG 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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28 AUG 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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04 SEP 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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 <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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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07 SEP 2022 00:01

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11 SEP 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 761
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 SEP 2022 00:01

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18 SEP 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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25 SEP 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 775
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT	DAY 789
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3412259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:35:32

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		03 MAR 2021 15:26:05

US3412259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

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

SUBJECT WAS IN ILLNESS
PHASE DURING THIS TIME

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

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

PATIENT NOT CALLED DUE TO
SITE ERROR. SITE STAFF
INSTRUCTED TO COMPLETE
REGULAR SAFETY CALLS
ALONGSIDE OPEN LABEL
PHASE

US3412259

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	08:14 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 08:14
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 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)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

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

Collection date (dd MMM yyyy)	25 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	08:25 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	25 MAR 2021 08:25
------------------------------------	-------------------

US3412259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:57:10

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

Date of Contact	09 NOV 2020
Time of Contact	13:00
Date and Time of Contact (derived)	09 NOV 2020 13:00
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>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

317 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	04 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	05 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

325 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	06 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

329 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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)

333 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	08 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	09 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	36.8 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 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 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.2 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

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Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	93 %	
O2 Saturation Units	%	
Temperature	96.4 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

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Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

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Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	91 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

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Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

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Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	99.1 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	96.3 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.0 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)

365 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.4 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)

373 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 type="checkbox"/>
Day 17	<input checked="" 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 NOV 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	97.4 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)

381 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input checked="" 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	96.1 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

385 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input checked="" 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 NOV 2020
------	-------------

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

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

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

Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input checked="" 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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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 NOV 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	97.1 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"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

393 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

	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"/>

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

Date of Visit 09 NOV 2020

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

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

Date of Test 09 NOV 2020

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

Other, specify

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

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 1

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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 11 NOV 2020

End Date 12 NOV 2020

Oxygen Saturation 91 %

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 _____

PRODUCTION RELEASE (v12.003

EAB) (1725)

397 of 2761

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Apr 2021 14:56:46

Generated On: 11 Aug 2021 22:35:32

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	11 NOV 2020
Day 5	Yes	13 NOV 2020
Day 7	Yes	15 NOV 2020
Day 9	Yes	17 NOV 2020
Day 14	Yes	22 NOV 2020
Day 21	Yes	29 NOV 2020
Day 28	Yes	03 DEC 2020

US3412259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	SICKD1

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 NOV 2020
Time of assessment (00:00-23:59)	13:23 (24 HR)
Vital Signs Date and Time (derived)	9 NOV 2020 13:23
Height (xxx.x)	164.0 cm
Weight (xxx.x)	69.5 kg
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:56:46

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 NOV 2020

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

US3412259

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:56:46

Generated On: 11 Aug 2021 22:35:32

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

9 NOV 2020

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD28

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 DEC 2020
Time of assessment (00:00-23:59)	09:11 (24 HR)
Vital Signs Date and Time (derived)	3 DEC 2020 09:11
Height (xxx.x)	163.0 cm
Weight (xxx.x)	69.3 kg
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 DEC 2020

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

US3412259

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 16 Apr 2021 14:56:45

Generated On: 11 Aug 2021 22:35:32

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

3 DEC 2020

US3412259

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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

Visit date (dd MMM yyyy)	18 JAN 2021
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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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US3412259

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Date of updated informed consent (<i>dd MMM yyyy</i>)	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3412259

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Height	163.5 cm
Weight	68.3 kg
BMI (xxx.x)	25.54966

US3412259

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Height	163.5 cm
Weight	68.3 kg
BMI (xxx.x)	25.54966
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)	18 JAN 2021
Time of assessment (00:00-23:59)	8:57 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 8:57
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Height	163.5 cm
Weight	68.3 kg
BMI (xxx.x)	25.54966
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)	18 JAN 2021
Time of assessment (00:00-23:59)	9:40 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 9:40
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

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

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3412259

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 9:09 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 9:09

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

US3412259

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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

Collection date (dd MMM yyyy)	18 JAN 2021
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Collection time (00:00-23:59)	8:32 (24 HR)
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Collection date and time (derived)	18 JAN 2021 8:32
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US3412259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	8:34
Collection Date and Time (derived)	18 JAN 2021 8:34

US3412259

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

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3412259

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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	OLD29

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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)	25 FEB 2021
Time of assessment (00:00-23:59)	07:22 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 07:22
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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)	25 FEB 2021
Time of assessment (00:00-23:59)	09:36 (24 HR)
Vital Signs Date and Time (derived)	25 FEB 2021 09:36
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412259

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 FEB 2021

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

US3412259

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

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? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 25 FEB 2021

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

Treatment Date and Time (derived) 25 FEB 2021 08:59

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

US3412259

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:38:53

Generated On: 11 Aug 2021 22:35:32

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412259

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	25 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	08:14 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 08:14
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412259

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 MAR 2021

Collection time (00:00-23:59)

08:25 (24 HR)

Collection date and time (derived)

25 MAR 2021 08:25

US3412259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

AEID	USA-US061-2020-MRNA-1273-P30 1000013
Adverse event	SYMPTOMATIC 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)	3 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

435 of 2761

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

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	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

ONSET OF COVID-19 LIKE
ILLNESS 03-NOV-2020 WITH
MILD SORE THROAT. ON
05-NOV-2020 SHE DEVELOPED
MILD NASAL CONGESTION
BODY ACHES AND RUNNY
NOSE. SHE WAS
ADMINISTERED A RAPID
COVID TEST BY HER WORK
AND RECEIVED NOTICE OF A
POSITIVE COVID TEST ON
FRIDAY 06-NOV-2020. THIS
SYMPTOMATIC COVID AE HAS
ENDED AS OF 17 NOV 2020 DUE
TO SUBJECT NOT
EXPERIENCING ANY MORE
SYMPTOMS.

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)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

AEID	
Adverse event	ONYCHOMYCOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003
EAB) (1725)

438 of 2761

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 15 Mar 2021 15:38:24

Generated On: 11 Aug 2021 22:35:32

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" 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)	_____

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:42:01

Generated On: 11 Aug 2021 22:35:32

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

Yes ☒

No ☐

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

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication IMITREX

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

441 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication CELECOXID-CELEBREX

Prophylaxis Yes ☐
No ☒

Indication OA-SHOULDER PAIN

Dose per administration 200

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

443 of 2761

EAB) (1725)

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)		12 JAN 2020
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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

445 of 2761

EAB) (1725)

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)		08 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		08 OCT 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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication SUDAFED - 12 HOUR

Prophylaxis Yes ☐
No ☒

Indication SYMPTOMATIC COVID-19 -
RUNNY NOSE AND
CONGESTION

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

447 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)	08 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	9 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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication PNEUMOVAX

Prophylaxis Yes ☒
No ☐

Indication PNEUMONIA 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

449 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)		05 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 DEC 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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication METHYL PREGNAZOLONE

Prophylaxis Yes ☐
No ☒

Indication RIGHT SHOULDER PAIN

Dose per administration 80

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)

451 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)		5 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		5 DEC 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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication TERBINAFINE HCL

Prophylaxis Yes ☐
No ☒

Indication ONYCHOMYCOSIS

Dose per administration 250

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)

453 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)	02 MAR 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"/>

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

Name of Medication EXCEDRIN
(ASPIRIN/CAFFEINE/ACETAMIN
OPHEN)

Prophylaxis Yes ☐
No ☒

Indication MIGRAIN

Dose per administration 250/65/250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

455 of 2761

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:42:31

Generated On: 11 Aug 2021 22:35:32

	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)	UN UNK 1988	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:42:01

Generated On: 11 Aug 2021 22:35:32

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3412259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:35:32

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

US3412259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:35:32

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 ☐

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	20/NOV/2020 19:56
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

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/DEC/2020 14:05
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

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:38
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

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 12:33
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

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 14:56:47

Generated On: 11 Aug 2021 22:35:32

SAEID	USA-US061-2020-MRNA-1273-P301000013
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	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	10/MAR/2021 08:38
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

US3412259 (Prod: New Horizons Clinical Research)

US3412259

Form: Participant Creation

Generated On: 11 Aug 2021 22:35:32

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'US3412259'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:19:35

US3412259

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:35:59

US3412259

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:19:36

US3412259

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:35:59

US3412259

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'SCRN'	System	17 Aug 2020 18:35:59

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered (b) (6) 1953'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:19:37

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '67'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'YEARS'	System	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '67'	System	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'I'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:35:32

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:13

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Aug 2020'	System	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2020'	System	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Amendment 2 (2)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:29

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 17:19:36

US3412259

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:35:32

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'I'	System	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:35:32

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:23:58

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 16:11:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 16:11:39
Data point term sent to Coder	System	24 Aug 2020 14:24:51
User entered 'HEADAHCE MIGRAINE'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'UN UNK 1963'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 1963'	System	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '1963'	System	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered empty.	System	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered empty.	System	24 Aug 2020 14:24:29

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Shoulder osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 14:26:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 14:26:42
Data point term sent to Coder	System	24 Aug 2020 14:25:52
User entered 'OSTEOARTHRITIS RIGHT SHOULDER'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 2015'	System	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2015'	System	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered empty.	System	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered empty.	System	24 Aug 2020 14:25:13

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female malignant and unspecified, HLT: Ovarian neoplasms malignant (excl germ cell), PT: Ovarian cancer, LLT: Ovarian cancer - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 15:35:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 15:35:00
Data point term sent to Coder	System	26 Oct 2020 14:11:46
User entered 'CANCER HISTORY (OVARIAN)'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'UN UNK 2002'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'UN UNK 2003'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Melissa Fuson (b) (4)	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 2002'	System	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mylene Asmar-Rios	24 Aug 2020 14:26:37
	(b) (4)	

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2002'	System	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 2003'	System	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	Mylene Asmar-Rios	24 Aug 2020 14:26:37
	(b) (4)	

US3412259

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2003'	System	26 Oct 2020 14:10:50
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	26 Oct 2020 14:10:14
DataPoint inactivated with code reason code Data not required.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:26:37

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:06:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:06:43
Data point term sent to Coder	System	20 Oct 2020 21:06:02
User entered 'Hysterectomy'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'un UNK 2003'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'un UNK 2003'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Steven Anderson (b) (4)	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 2003'	System	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2003'	System	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'Jan 2003'	System	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '2003'	System	20 Oct 2020 21:05:11

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '13:28'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '17 Aug 2020 13:28'	System	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '164.5' cm	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:27:51
DataPoint set to visible.	(b) (4) System	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '71.5' kg	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:27:51
DataPoint set to visible.	(b) (4) System	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
Amendment Manager: User entered '26.42252'	System	17 Sep 2020 00:00:15
User entered '26.4'	System	24 Aug 2020 14:27:51
DataPoint set to visible.	System	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'kg/m2'	System	24 Aug 2020 14:27:51
DataPoint set to visible.	System	17 Aug 2020 18:36:36

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Sep 2020 21:32:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 21:32:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Aug 2020 14:27:51
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Sep 2020 21:32:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 21:32:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Aug 2020 14:27:51
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'bpm'	System	24 Sep 2020 21:32:45
User entered empty.	System	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Sep 2020 21:32:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 21:32:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	24 Aug 2020 14:27:51
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'breaths/min'	System	24 Sep 2020 21:32:45
User entered empty.	System	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 21:32:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 21:32:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 14:27:51
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'mmHg'	System	24 Sep 2020 21:32:45
User entered empty.	System	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Sep 2020 21:32:45
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	24 Sep 2020 21:32:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Jacob sekinger (b) (4)	24 Sep 2020 21:32:45
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 14:27:51
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'mmHg'	System	24 Sep 2020 21:32:45
User entered empty.	System	24 Aug 2020 14:27:51

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29

US3412259

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29

US3412259

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:28:13

US3412259

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:28:13

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:29:22
	(b) (4)	

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Per DM CLR/Requery: However, please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 05:23:38
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	21 Dec 2020 14:27:40
Query 'Per DM CLR/Requery: However, please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' answered with 'subject had hysterectomy in 2003.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:26:39
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	21 Dec 2020 14:24:53
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 14:24:53
User opened query 'Per DM CLR/Requery: However, please review this condition as this is not recorded in MH eCRF. Record this condition in MH eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 11:50:42
User closed query 'Per DM CLR: Note, If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).		21 Oct 2020 13:27:49

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Per subject medical history, subject's last minstrel period was in 1997 which took place before her surgery of 2003' (Site from DM). User closed query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	Steven Anderson (b) (4)	20 Oct 2020 21:06:35
User opened query 'Surgically sterile has not been entered, however date of surgery is provided, or Date of surgery unknown is checked. Please correct.' (Site from System).	System	20 Oct 2020 21:05:40
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	System	20 Oct 2020 21:05:23
User entered 'Post-menopausal (POST-MENOPAUSAL)' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Oct 2020 21:05:23
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 05:44:24
User entered 'Surgically sterile (SURGICALLY STERILE)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	21 Dec 2020 14:26:57
User entered 'un UNK 2003' reason for change: Data Entry Error	Melissa Fuson (b) (4)	21 Dec 2020 14:26:57
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	21 Dec 2020 14:24:53
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	20 Oct 2020 21:05:40
User entered 'UN UNK 1997' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Oct 2020 21:05:23
User entered 'UN UNK 2003'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

If Post-menopausal, date of last menstruation (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	21 Dec 2020 14:27:40
User closed query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	20 Oct 2020 21:05:40
User entered 'un UNK 1997' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Oct 2020 21:05:40
User opened query 'Post-menopausal has been entered, however date of last menstruation is missing. Please provide.' (Site from System).	System	20 Oct 2020 21:05:23
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:35:32

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:29:22

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:34:32
	(b) (4)	

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:34:32
	(b) (4)	

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) Mylene Asmar-Rios	24 Aug 2020 14:34:32
	(b) (4)	

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	(b) (4)	24 Aug 2020 14:34:45
User opened query "No Risk Identified" is not checked, however no other risks are selected. Please review and reconcile.' (Site from System).	System	24 Aug 2020 14:34:32
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '1' reason for change: Data Entry Error	(b) (4)	24 Aug 2020 14:34:45
User entered '0'	Mylene Asmar-Rios	24 Aug 2020 14:34:32
	(b) (4)	

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:35:32

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:32

US3412259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 18:36:52

US3412259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:52

US3412259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:36:52

US3412259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'VISIT1'	System	17 Aug 2020 18:36:52

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:14:31

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 05:03:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:03:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 18:14:31
User entered '186364' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:14:31

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 18:14:31

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:03

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:03

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 18:37:03

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:03

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:03

US3412259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Jacob sekinger (b) (4)	24 Sep 2020 21:33:09
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:57
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:40:51

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '13:28' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '17 Aug 2020 13:28'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '36.8' C reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	24 Aug 2020 15:31:31
User entered empty.	Mylene Asmar-Rios	24 Aug 2020 14:35:36
	(b) (4)	

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '74' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'bpm'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '14' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'breaths/min'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '126' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '86' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered missing code ND - Not Done.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	Mylene Asmar-Rios	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '14:51' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '17 Aug 2020 14:51'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
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)	29 Sep 2020 13:06:13
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 'temperature within normal range. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 21:33:29
Amendment Manager: 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	17 Sep 2020 00:00:15
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 15:31:31
User entered '96.5' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	24 Aug 2020 15:31:31
User entered empty.	Mylene Asmar-Rios	24 Aug 2020 14:35:36
	(b) (4)	

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '70' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'bpm'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '15' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'breaths/min'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '130' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	24 Aug 2020 15:31:31
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	24 Aug 2020 15:31:31
User entered '80' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:31:31
User opened query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 14:35:36
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Aug 2020 15:31:31
User entered empty.	System	24 Aug 2020 14:35:36

US3412259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:58

US3412259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 14:34:58

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '14:20'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '17 Aug 2020 14:20'	System	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'ONCE'	System	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 18:37:41

US3412259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:28:42

US3412259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:28:42

US3412259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '14:00'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:28:42

US3412259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '17 Aug 2020 14:00'	System	24 Aug 2020 23:28:42

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '14:05'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '17 Aug 2020 14:05'	System	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	24 Aug 2020 23:29:01

US3412259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:10

US3412259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '1'	System	24 Aug 2020 23:29:10

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:57:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f807870f-12c2-431d-b269-c4c64185d1e3' User entered 'Yes (Y)'	System	17 Aug 2020 18:57:44
	System	17 Aug 2020 18:57:44

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:57:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f807870f-12c2-431d-b269-c4c64185d1e3' User entered '96.5'	System	17 Aug 2020 18:57:44
	System	17 Aug 2020 18:57:44

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:57:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f807870f-12c2-431d-b269-c4c64185d1e3'	System	17 Aug 2020 18:57:44
User entered 'No (N)'	System	17 Aug 2020 18:57:44

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:57:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f807870f-12c2-431d-b269-c4c64185d1e3'	System	17 Aug 2020 18:57:44
User entered '17 Aug 2020 14:57'	System	17 Aug 2020 18:57:44

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 14:40'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 17:10'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:32:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7000bb31-8a86-4e6c-86d4-6edc2a0e9d5b' User entered 'Yes (Y)'	System	18 Aug 2020 00:32:46
	System	18 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:32:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7000bb31-8a86-4e6c-86d4-6edc2a0e9d5b' User entered '96.4'	System	18 Aug 2020 00:32:46
	System	18 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:32:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7000bb31-8a86-4e6c-86d4-6edc2a0e9d5b'	System	18 Aug 2020 00:32:46
User entered 'No (N)'	System	18 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:32:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7000bb31-8a86-4e6c-86d4-6edc2a0e9d5b' User entered '17 Aug 2020 20:32'	System	18 Aug 2020 00:32:46
	System	18 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 18:05'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 2'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:27:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9852daf3-088e-4d96-a066-705ec8102488' User entered 'Yes (Y)'	System	19 Aug 2020 00:28:56
	System	19 Aug 2020 00:28:56

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:28:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9852daf3-088e-4d96-a066-705ec8102488'	System	19 Aug 2020 00:28:56
User entered '95.9'	System	19 Aug 2020 00:28:56

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:28:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9852daf3-088e-4d96-a066-705ec8102488'	System	19 Aug 2020 00:28:56
User entered 'No (N)'	System	19 Aug 2020 00:28:56

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:28:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9852daf3-088e-4d96-a066-705ec8102488'	System	19 Aug 2020 00:28:56
User entered '18 Aug 2020 20:28'	System	19 Aug 2020 00:28:56

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 3'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:31:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f7c909c0-75e4-4b39-9257-94ac7b794f6f' User entered 'Yes (Y)'	System	20 Aug 2020 00:35:04
	System	20 Aug 2020 00:35:04

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:34:52', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f7c909c0-75e4-4b39-9257-94ac7b794f6f' User entered '97.0'	System	20 Aug 2020 00:35:04
	System	20 Aug 2020 00:35:04

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:34:56', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f7c909c0-75e4-4b39-9257-94ac7b794f6f' User entered 'No (N)'	System	20 Aug 2020 00:35:04
	System	20 Aug 2020 00:35:04

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:01', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f7c909c0-75e4-4b39-9257-94ac7b794f6f' User entered '19 Aug 2020 20:35'	System	20 Aug 2020 00:35:04
	System	20 Aug 2020 00:35:04

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 4'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:29:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '60dd4c8a-2613-4aa0-8958-f502d0d2d83e' User entered 'Yes (Y)'	System	21 Aug 2020 00:29:51
	System	21 Aug 2020 00:29:51

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:29:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '60dd4c8a-2613-4aa0-8958-f502d0d2d83e' User entered '96.8'	System	21 Aug 2020 00:29:51
	System	21 Aug 2020 00:29:51

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:29:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '60dd4c8a-2613-4aa0-8958-f502d0d2d83e' User entered 'No (N)'	System	21 Aug 2020 00:29:51
	System	21 Aug 2020 00:29:51

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:29:49', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '60dd4c8a-2613-4aa0-8958-f502d0d2d83e' User entered '20 Aug 2020 20:29'	System	21 Aug 2020 00:29:51
	System	21 Aug 2020 00:29:51

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 5'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:16', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd06ed451-7d10-498a-8b6f-5918d4d7f6c2'	System	22 Aug 2020 00:16:42
User entered 'Yes (Y)'	System	22 Aug 2020 00:16:42

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:23', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd06ed451-7d10-498a-8b6f-5918d4d7f6c2'	System	22 Aug 2020 00:16:42
User entered '95.8'	System	22 Aug 2020 00:16:42

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:34', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd06ed451-7d10-498a-8b6f-5918d4d7f6c2'	System	22 Aug 2020 00:16:42
User entered 'No (N)'	System	22 Aug 2020 00:16:42

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd06ed451-7d10-498a-8b6f-5918d4d7f6c2'	System	22 Aug 2020 00:16:42
User entered '21 Aug 2020 20:16'	System	22 Aug 2020 00:16:42

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 6'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e123c87b-cbff-4652-b6ed-6a4155251485' User entered 'Yes (Y)'	System	23 Aug 2020 00:34:41
	System	23 Aug 2020 00:34:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:28', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e123c87b-cbff-4652-b6ed-6a4155251485' User entered '96.2'	System	23 Aug 2020 00:34:41
	System	23 Aug 2020 00:34:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e123c87b-cbff-4652-b6ed-6a4155251485'	System	23 Aug 2020 00:34:41
User entered 'No (N)'	System	23 Aug 2020 00:34:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e123c87b-cbff-4652-b6ed-6a4155251485' User entered '22 Aug 2020 20:34'	System	23 Aug 2020 00:34:41
	System	23 Aug 2020 00:34:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 7'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:31:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dddec96-ec5e-4eef-9d5d-7566effc2660'	System	24 Aug 2020 00:32:25
User entered 'Yes (Y)'	System	24 Aug 2020 00:32:25

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dddec96-ec5e-4eef-9d5d-7566effc2660'	System	24 Aug 2020 00:32:25
User entered '96.1'	System	24 Aug 2020 00:32:25

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dddec96-ec5e-4eef-9d5d-7566effc2660'	System	24 Aug 2020 00:32:25
User entered 'No (N)'	System	24 Aug 2020 00:32:25

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:23', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dddec96-ec5e-4eef-9d5d-7566effc2660'	System	24 Aug 2020 00:32:25
User entered '23 Aug 2020 20:32'	System	24 Aug 2020 00:32:25

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:58:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5d2b9b06-cf40-4866-8152-1fc1643d7a28' User entered 'None (1)'	System	17 Aug 2020 18:59:09
	System	17 Aug 2020 18:59:09

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:58:49', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5d2b9b06-cf40-4866-8152-1fc1643d7a28' User entered 'No (N)'	System	17 Aug 2020 18:59:09
	System	17 Aug 2020 18:59:09

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:58:52', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5d2b9b06-cf40-4866-8152-1fc1643d7a28' User entered 'No (N)'	System	17 Aug 2020 18:59:09
	System	17 Aug 2020 18:59:09

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5d2b9b06-cf40-4866-8152-1fc1643d7a28' User entered 'None (1)'	System	17 Aug 2020 18:59:09
	System	17 Aug 2020 18:59:09

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:07', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5d2b9b06-cf40-4866-8152-1fc1643d7a28' User entered '17 Aug 2020 14:59'	System	17 Aug 2020 18:59:09
	System	17 Aug 2020 18:59:09

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 14:40'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 17:10'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b100e635-eacc-4f27-9a0b-5389797172d1' User entered 'None (1)'	System	18 Aug 2020 00:33:22
	System	18 Aug 2020 00:33:22

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:32:54', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b100e635-eacc-4f27-9a0b-5389797172d1' User entered 'No (N)'	System	18 Aug 2020 00:33:22
	System	18 Aug 2020 00:33:22

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:08', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b100e635-eacc-4f27-9a0b-5389797172d1' User entered 'No (N)'	System	18 Aug 2020 00:33:22
	System	18 Aug 2020 00:33:22

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b100e635-eacc-4f27-9a0b-5389797172d1' User entered 'None (1)'	System	18 Aug 2020 00:33:22
	System	18 Aug 2020 00:33:22

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b100e635-eacc-4f27-9a0b-5389797172d1'	System	18 Aug 2020 00:33:22
User entered '17 Aug 2020 20:33'	System	18 Aug 2020 00:33:22

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 18:05'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 2'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '194540c4-5971-449e-8c8c-c5270a46399a' User entered 'None (1)'	System	19 Aug 2020 00:29:42
	System	19 Aug 2020 00:29:42

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '194540c4-5971-449e-8c8c-c5270a46399a' User entered 'No (N)'	System	19 Aug 2020 00:29:42
	System	19 Aug 2020 00:29:42

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '194540c4-5971-449e-8c8c-c5270a46399a' User entered 'No (N)'	System	19 Aug 2020 00:29:42
	System	19 Aug 2020 00:29:42

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '194540c4-5971-449e-8c8c-c5270a46399a' User entered 'None (1)'	System	19 Aug 2020 00:29:42
	System	19 Aug 2020 00:29:42

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '194540c4-5971-449e-8c8c-c5270a46399a' User entered '18 Aug 2020 20:29'	System	19 Aug 2020 00:29:42
	System	19 Aug 2020 00:29:42

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 3'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:06', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4b4fab05-ae89-4bec-a4fd-40da93c02d2f' User entered 'None (1)'	System	20 Aug 2020 00:35:24
	System	20 Aug 2020 00:35:24

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:09', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4b4fab05-ae89-4bec-a4fd-40da93c02d2f' User entered 'No (N)'	System	20 Aug 2020 00:35:24
	System	20 Aug 2020 00:35:24

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:11', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4b4fab05-ae89-4bec-a4fd-40da93c02d2f' User entered 'No (N)'	System	20 Aug 2020 00:35:24
	System	20 Aug 2020 00:35:24

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:15', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4b4fab05-ae89-4bec-a4fd-40da93c02d2f' User entered 'None (1)'	System	20 Aug 2020 00:35:24
	System	20 Aug 2020 00:35:24

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:22', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4b4fab05-ae89-4bec-a4fd-40da93c02d2f' User entered '19 Aug 2020 20:35'	System	20 Aug 2020 00:35:24
	System	20 Aug 2020 00:35:24

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 4'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:29:59', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7e5570f4-fbf3-4425-beb9-ad37a9ed3e06'	System	21 Aug 2020 00:30:36
User entered 'None (1)'	System	21 Aug 2020 00:30:36

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7e5570f4-fbf3-4425-beb9-ad37a9ed3e06'	System	21 Aug 2020 00:30:36
User entered 'No (N)'	System	21 Aug 2020 00:30:36

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7e5570f4-fbf3-4425-beb9-ad37a9ed3e06'	System	21 Aug 2020 00:30:36
User entered 'No (N)'	System	21 Aug 2020 00:30:36

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:22', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7e5570f4-fbf3-4425-beb9-ad37a9ed3e06'	System	21 Aug 2020 00:30:36
User entered 'None (1)'	System	21 Aug 2020 00:30:36

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7e5570f4-fbf3-4425-beb9-ad37a9ed3e06'	System	21 Aug 2020 00:30:36
User entered '20 Aug 2020 20:30'	System	21 Aug 2020 00:30:36

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 5'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8ea8c0ec-a343-4561-b629-281a52b40af6'	System	22 Aug 2020 00:17:02
User entered 'None (1)'	System	22 Aug 2020 00:17:02

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8ea8c0ec-a343-4561-b629-281a52b40af6'	System	22 Aug 2020 00:17:02
User entered 'No (N)'	System	22 Aug 2020 00:17:02

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8ea8c0ec-a343-4561-b629-281a52b40af6' User entered 'No (N)'	System	22 Aug 2020 00:17:02
	System	22 Aug 2020 00:17:02

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:54', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8ea8c0ec-a343-4561-b629-281a52b40af6' User entered 'None (1)'	System	22 Aug 2020 00:17:02
	System	22 Aug 2020 00:17:02

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:16:59', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8ea8c0ec-a343-4561-b629-281a52b40af6'	System	22 Aug 2020 00:17:02
User entered '21 Aug 2020 20:16'	System	22 Aug 2020 00:17:02

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 6'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:51', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a42c963c-fd6e-494d-a89f-329c7344f6f5' User entered 'None (1)'	System	23 Aug 2020 00:35:15
	System	23 Aug 2020 00:35:15

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:34:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a42c963c-fd6e-494d-a89f-329c7344f6f5' User entered 'No (N)'	System	23 Aug 2020 00:35:15
	System	23 Aug 2020 00:35:15

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a42c963c-fd6e-494d-a89f-329c7344f6f5' User entered 'No (N)'	System	23 Aug 2020 00:35:15
	System	23 Aug 2020 00:35:15

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:08', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a42c963c-fd6e-494d-a89f-329c7344f6f5' User entered 'None (1)'	System	23 Aug 2020 00:35:15
	System	23 Aug 2020 00:35:15

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a42c963c-fd6e-494d-a89f-329c7344f6f5'	System	23 Aug 2020 00:35:15
User entered '22 Aug 2020 20:35'	System	23 Aug 2020 00:35:15

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 7'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e7e3c549-69c5-4625-bb43-d3cca362c784'	System	24 Aug 2020 00:32:46
User entered 'None (1)'	System	24 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e7e3c549-69c5-4625-bb43-d3cca362c784' User entered 'No (N)'	System	24 Aug 2020 00:32:46
	System	24 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e7e3c549-69c5-4625-bb43-d3cca362c784' User entered 'No (N)'	System	24 Aug 2020 00:32:46
	System	24 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e7e3c549-69c5-4625-bb43-d3cca362c784'	System	24 Aug 2020 00:32:46
User entered 'None (1)'	System	24 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e7e3c549-69c5-4625-bb43-d3cca362c784' User entered '23 Aug 2020 20:32'	System	24 Aug 2020 00:32:46
	System	24 Aug 2020 00:32:46

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:16', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:19', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e' User entered 'None (0)'	System	17 Aug 2020 18:59:42
	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e'	System	17 Aug 2020 18:59:42
User entered 'No (N)'	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T14:59:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd6917496-15cb-4a28-8a20-49191b8b2e5e'	System	17 Aug 2020 18:59:42
User entered '17 Aug 2020 14:59'	System	17 Aug 2020 18:59:42

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 14:40'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 17:10'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:28', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'None (0)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:47', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered 'No (N)'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-17T20:33:58', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a44803e2-878a-4b26-adcb-7e13e1619727'	System	18 Aug 2020 00:34:02
User entered '17 Aug 2020 20:33'	System	18 Aug 2020 00:34:02

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '17 Aug 2020 18:05'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 2'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51'	System	19 Aug 2020 00:30:14
User entered 'None (0)'	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:47', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51' User entered 'None (0)'	System	19 Aug 2020 00:30:14
	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51' User entered 'None (0)'	System	19 Aug 2020 00:30:14
	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51' User entered 'None (0)'	System	19 Aug 2020 00:30:14
	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51' User entered 'None (0)'	System	19 Aug 2020 00:30:14
	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:29:58', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51' User entered 'None (0)'	System	19 Aug 2020 00:30:14
	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:30:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51'	System	19 Aug 2020 00:30:14
User entered 'No (N)'	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-18T20:30:09', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bde1b8bf-c80a-4571-a733-9d69345fde51'	System	19 Aug 2020 00:30:14
User entered '18 Aug 2020 20:30'	System	19 Aug 2020 00:30:14

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 3'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered 'None (0)'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered 'None (0)'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:33', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered 'None (0)'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered 'None (0)'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:42', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689' User entered 'None (0)'	System	20 Aug 2020 00:35:58
	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689' User entered 'None (0)'	System	20 Aug 2020 00:35:58
	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered 'No (N)'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-19T20:35:56', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'c4a49732-9efa-4c2d-bb83-457398648689'	System	20 Aug 2020 00:35:58
User entered '19 Aug 2020 20:35'	System	20 Aug 2020 00:35:58

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 4'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327' User entered 'None (0)'	System	21 Aug 2020 00:31:24
	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered 'None (0)'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:47', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327' User entered 'None (0)'	System	21 Aug 2020 00:31:24
	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered 'None (0)'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered 'None (0)'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:30:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered 'None (0)'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:31:08', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered 'No (N)'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-20T20:31:20', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a01191bd-1b5c-4c36-842c-c360388d3327'	System	21 Aug 2020 00:31:24
User entered '20 Aug 2020 20:31'	System	21 Aug 2020 00:31:24

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 5'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf'	System	22 Aug 2020 00:17:29
User entered 'None (0)'	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:05', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf'	System	22 Aug 2020 00:17:29
User entered 'None (0)'	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:10', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf'	System	22 Aug 2020 00:17:29
User entered 'None (0)'	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf' User entered 'None (0)'	System	22 Aug 2020 00:17:29
	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:15', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf'	System	22 Aug 2020 00:17:29
User entered 'None (0)'	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf' User entered 'None (0)'	System	22 Aug 2020 00:17:29
	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf'	System	22 Aug 2020 00:17:29
User entered 'No (N)'	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-21T20:17:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bee4337f-056d-401e-9302-47c800bff3bf' User entered '21 Aug 2020 20:17'	System	22 Aug 2020 00:17:29
	System	22 Aug 2020 00:17:29

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 6'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:25', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:30', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:32', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:34', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'None (0)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered 'No (N)'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-22T20:35:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'bae80e24-bc92-456a-8644-0a9cf662d78d' User entered '22 Aug 2020 20:35'	System	23 Aug 2020 00:35:47
	System	23 Aug 2020 00:35:47

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 7'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered 'None (0)'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered 'None (0)'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered 'None (0)'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:57', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered 'None (0)'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:32:59', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583'	System	24 Aug 2020 00:33:12
User entered 'None (0)'	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:33:01', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered 'None (0)'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:33:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583'	System	24 Aug 2020 00:33:12
User entered 'No (N)'	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-08-23T20:33:06', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5178e5c1-dbab-4ca7-8e6a-884a2838d583' User entered '23 Aug 2020 20:33'	System	24 Aug 2020 00:33:12
	System	24 Aug 2020 00:33:12

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 18:37:41

US3412259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:52

US3412259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:52

US3412259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:52

US3412259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:52

US3412259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 23:29:57

US3412259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	24 Aug 2020 23:29:57

US3412259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:42:52

US3412259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:42:52

US3412259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:42:52

US3412259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:42:52

US3412259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 21:42:57

US3412259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	31 Aug 2020 21:42:57

US3412259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Sep 2020 17:12:55

US3412259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '8 Sep 2020'	Mason Urban (b) (4)	08 Sep 2020 17:12:55

US3412259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	08 Sep 2020 17:12:55

US3412259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mason Urban (b) (4)	08 Sep 2020 17:12:55

US3412259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	08 Sep 2020 17:13:02

US3412259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	08 Sep 2020 17:13:02

US3412259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 13:26:24

US3412259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:26:24

US3412259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:26:24

US3412259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'VISIT2'	System	21 Sep 2020 13:26:24

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '8:48'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '21 Sep 2020 8:48'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '36.6' C	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '64'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'bpm'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '16'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'breaths/min'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '136'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '86'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '9:58'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '21 Sep 2020 9:58'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '96.8' F	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '62'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'bpm'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '18'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'breaths/min'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '132'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '88'	Jacob sekinger (b) (4)	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'mmHg'	System	24 Sep 2020 21:30:43

US3412259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:26:39

US3412259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:26:39

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '09:25'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '21 Sep 2020 09:25'	System	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'ONCE'	System	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 13:27:03

US3412259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:22

US3412259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:22

US3412259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '08:55'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:22

US3412259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '21 Sep 2020 08:55'	System	21 Sep 2020 13:27:22

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '21 Sep 2020'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '09:00'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '21 Sep 2020 09:00'	System	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	21 Sep 2020 13:27:40

US3412259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Sep 2020 13:27:45

US3412259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	21 Sep 2020 13:27:45

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5e042909-e415-46fd-be7d-3cb059f4c42e' User entered 'Yes (Y)'	System	21 Sep 2020 13:59:36
	System	21 Sep 2020 13:59:36

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:20', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5e042909-e415-46fd-be7d-3cb059f4c42e' User entered '96.8'	System	21 Sep 2020 13:59:36
	System	21 Sep 2020 13:59:36

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5e042909-e415-46fd-be7d-3cb059f4c42e' User entered 'No (N)'	System	21 Sep 2020 13:59:36
	System	21 Sep 2020 13:59:36

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '5e042909-e415-46fd-be7d-3cb059f4c42e' User entered '21 Sep 2020 09:59'	System	21 Sep 2020 13:59:36
	System	21 Sep 2020 13:59:36

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:03:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '666bbcd4-535e-46f8-a501-07d24e60a610'	System	22 Sep 2020 00:03:44
User entered 'Yes (Y)'	System	22 Sep 2020 00:03:44

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:03:30', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '666bbcd4-535e-46f8-a501-07d24e60a610' User entered '96.5'	System	22 Sep 2020 00:03:44
	System	22 Sep 2020 00:03:44

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:03:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '666bbcd4-535e-46f8-a501-07d24e60a610' User entered 'No (N)'	System	22 Sep 2020 00:03:44
	System	22 Sep 2020 00:03:44

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:03:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '666bbcd4-535e-46f8-a501-07d24e60a610' User entered '21 Sep 2020 20:03'	System	22 Sep 2020 00:03:44
	System	22 Sep 2020 00:03:44

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 2'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:20:49', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dcd3c1be-7173-4067-9e8f-38ba82ba0e97'	System	23 Sep 2020 00:21:06
User entered 'Yes (Y)'	System	23 Sep 2020 00:21:06

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:20:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dcd3c1be-7173-4067-9e8f-38ba82ba0e97'	System	23 Sep 2020 00:21:06
User entered '96.3'	System	23 Sep 2020 00:21:06

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:20:59', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dcd3c1be-7173-4067-9e8f-38ba82ba0e97'	System	23 Sep 2020 00:21:06
User entered 'No (N)'	System	23 Sep 2020 00:21:06

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'dcd3c1be-7173-4067-9e8f-38ba82ba0e97'	System	23 Sep 2020 00:21:06
User entered '22 Sep 2020 20:21'	System	23 Sep 2020 00:21:06

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 3'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:01:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '52b7c61b-3ec9-4232-8289-e72b026be0a6' User entered 'Yes (Y)'	System	24 Sep 2020 00:02:22
	System	24 Sep 2020 00:02:22

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:01:56', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '52b7c61b-3ec9-4232-8289-e72b026be0a6' User entered '96.0'	System	24 Sep 2020 00:02:22
	System	24 Sep 2020 00:02:22

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '52b7c61b-3ec9-4232-8289-e72b026be0a6'	System	24 Sep 2020 00:02:22
User entered 'No (N)'	System	24 Sep 2020 00:02:22

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:19', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '52b7c61b-3ec9-4232-8289-e72b026be0a6'	System	24 Sep 2020 00:02:22
User entered '23 Sep 2020 20:02'	System	24 Sep 2020 00:02:22

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 4'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:30:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f44039e9-b3d0-455d-87b2-8b9a67b8abb4' User entered 'Yes (Y)'	System	25 Sep 2020 00:31:09
	System	25 Sep 2020 00:31:09

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f44039e9-b3d0-455d-87b2-8b9a67b8abb4' User entered '96.8'	System	25 Sep 2020 00:31:09
	System	25 Sep 2020 00:31:09

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f44039e9-b3d0-455d-87b2-8b9a67b8abb4' User entered 'No (N)'	System	25 Sep 2020 00:31:09
	System	25 Sep 2020 00:31:09

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:07', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f44039e9-b3d0-455d-87b2-8b9a67b8abb4'	System	25 Sep 2020 00:31:09
User entered '24 Sep 2020 20:31'	System	25 Sep 2020 00:31:09

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 5'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:01:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4aae235e-43d7-4264-a411-48f1afd3baaf' User entered 'Yes (Y)'	System	26 Sep 2020 00:01:53
	System	26 Sep 2020 00:01:53

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:01:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4aae235e-43d7-4264-a411-48f1afd3baaf' User entered '96.0'	System	26 Sep 2020 00:01:53
	System	26 Sep 2020 00:01:53

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:01:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4aae235e-43d7-4264-a411-48f1afd3baaf' User entered 'No (N)'	System	26 Sep 2020 00:01:53
	System	26 Sep 2020 00:01:53

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:01:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4aae235e-43d7-4264-a411-48f1afd3baaf' User entered '25 Sep 2020 20:01'	System	26 Sep 2020 00:01:53
	System	26 Sep 2020 00:01:53

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 6'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:08', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '56e69dd2-2154-49d2-9185-385e4954d889'	System	26 Sep 2020 23:14:40
User entered 'Yes (Y)'	System	26 Sep 2020 23:14:40

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '56e69dd2-2154-49d2-9185-385e4954d889' User entered '97.3'	System	26 Sep 2020 23:14:40
	System	26 Sep 2020 23:14:40

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:32', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '56e69dd2-2154-49d2-9185-385e4954d889'	System	26 Sep 2020 23:14:40
User entered 'No (N)'	System	26 Sep 2020 23:14:40

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '56e69dd2-2154-49d2-9185-385e4954d889'	System	26 Sep 2020 23:14:40
User entered '26 Sep 2020 19:14'	System	26 Sep 2020 23:14:40

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 7'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:02:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e52a0f89-4961-4c96-ae1f-470167490b3c' User entered 'Yes (Y)'	System	28 Sep 2020 00:03:20
	System	28 Sep 2020 00:03:20

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:10', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e52a0f89-4961-4c96-ae1f-470167490b3c' User entered '96.8'	System	28 Sep 2020 00:03:20
	System	28 Sep 2020 00:03:20

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:15', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e52a0f89-4961-4c96-ae1f-470167490b3c' User entered 'No (N)'	System	28 Sep 2020 00:03:20
	System	28 Sep 2020 00:03:20

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e52a0f89-4961-4c96-ae1f-470167490b3c' User entered '27 Sep 2020 20:03'	System	28 Sep 2020 00:03:20
	System	28 Sep 2020 00:03:20

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '27d08795-9674-406a-bea0-81a9f8099713' User entered 'None (1)'	System	21 Sep 2020 14:00:00
	System	21 Sep 2020 14:00:00

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '27d08795-9674-406a-bea0-81a9f8099713' User entered 'No (N)'	System	21 Sep 2020 14:00:00
	System	21 Sep 2020 14:00:00

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '27d08795-9674-406a-bea0-81a9f8099713' User entered 'No (N)'	System	21 Sep 2020 14:00:00
	System	21 Sep 2020 14:00:00

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '27d08795-9674-406a-bea0-81a9f8099713' User entered 'None (1)'	System	21 Sep 2020 14:00:00
	System	21 Sep 2020 14:00:00

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T09:59:58', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '27d08795-9674-406a-bea0-81a9f8099713' User entered '21 Sep 2020 09:59'	System	21 Sep 2020 14:00:00
	System	21 Sep 2020 14:00:00

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:20', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '061ed7d5-cb3e-4488-9dda-4d96735d5586' User entered 'None (1)'	System	22 Sep 2020 00:04:36
	System	22 Sep 2020 00:04:36

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:16', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '061ed7d5-cb3e-4488-9dda-4d96735d5586' User entered 'No (N)'	System	22 Sep 2020 00:04:36
	System	22 Sep 2020 00:04:36

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:16', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '061ed7d5-cb3e-4488-9dda-4d96735d5586' User entered 'No (N)'	System	22 Sep 2020 00:04:36
	System	22 Sep 2020 00:04:36

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '061ed7d5-cb3e-4488-9dda-4d96735d5586' User entered 'None (1)'	System	22 Sep 2020 00:04:36
	System	22 Sep 2020 00:04:36

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:34', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '061ed7d5-cb3e-4488-9dda-4d96735d5586'	System	22 Sep 2020 00:04:36
User entered '21 Sep 2020 20:04'	System	22 Sep 2020 00:04:36

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 2'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:09', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4e533c74-8740-4e80-9a73-f38f746b24d6'	System	23 Sep 2020 00:21:31
User entered 'None (1)'	System	23 Sep 2020 00:21:31

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4e533c74-8740-4e80-9a73-f38f746b24d6' User entered 'No (N)'	System	23 Sep 2020 00:21:31
	System	23 Sep 2020 00:21:31

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:14', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4e533c74-8740-4e80-9a73-f38f746b24d6' User entered 'No (N)'	System	23 Sep 2020 00:21:31
	System	23 Sep 2020 00:21:31

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4e533c74-8740-4e80-9a73-f38f746b24d6' User entered 'None (1)'	System	23 Sep 2020 00:21:31
	System	23 Sep 2020 00:21:31

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4e533c74-8740-4e80-9a73-f38f746b24d6'	System	23 Sep 2020 00:21:31
User entered '22 Sep 2020 20:21'	System	23 Sep 2020 00:21:31

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 3'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '66572965-9c88-432c-a92e-3adde6019c91'	System	24 Sep 2020 00:02:45
User entered 'None (1)'	System	24 Sep 2020 00:02:45

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:32', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '66572965-9c88-432c-a92e-3adde6019c91' User entered 'No (N)'	System	24 Sep 2020 00:02:45
	System	24 Sep 2020 00:02:45

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '66572965-9c88-432c-a92e-3adde6019c91' User entered 'No (N)'	System	24 Sep 2020 00:02:45
	System	24 Sep 2020 00:02:45

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '66572965-9c88-432c-a92e-3adde6019c91'	System	24 Sep 2020 00:02:45
User entered 'None (1)'	System	24 Sep 2020 00:02:45

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '66572965-9c88-432c-a92e-3adde6019c91'	System	24 Sep 2020 00:02:45
User entered '23 Sep 2020 20:02'	System	24 Sep 2020 00:02:45

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 4'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'da70d19e-0a2c-47fd-94b2-875b0a8964d1' User entered 'None (1)'	System	25 Sep 2020 00:31:30
	System	25 Sep 2020 00:31:30

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:15', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'da70d19e-0a2c-47fd-94b2-875b0a8964d1' User entered 'No (N)'	System	25 Sep 2020 00:31:30
	System	25 Sep 2020 00:31:30

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'da70d19e-0a2c-47fd-94b2-875b0a8964d1' User entered 'No (N)'	System	25 Sep 2020 00:31:30
	System	25 Sep 2020 00:31:30

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:22', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'da70d19e-0a2c-47fd-94b2-875b0a8964d1' User entered 'None (1)'	System	25 Sep 2020 00:31:30
	System	25 Sep 2020 00:31:30

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'da70d19e-0a2c-47fd-94b2-875b0a8964d1' User entered '24 Sep 2020 20:31'	System	25 Sep 2020 00:31:30
	System	25 Sep 2020 00:31:30

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 5'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:01:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9b480158-f9a1-44b6-8076-f201b26e8e5d' User entered 'None (1)'	System	26 Sep 2020 00:02:20
	System	26 Sep 2020 00:02:20

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:05', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9b480158-f9a1-44b6-8076-f201b26e8e5d' User entered 'No (N)'	System	26 Sep 2020 00:02:20
	System	26 Sep 2020 00:02:20

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:08', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9b480158-f9a1-44b6-8076-f201b26e8e5d' User entered 'No (N)'	System	26 Sep 2020 00:02:20
	System	26 Sep 2020 00:02:20

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:10', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9b480158-f9a1-44b6-8076-f201b26e8e5d' User entered 'None (1)'	System	26 Sep 2020 00:02:20
	System	26 Sep 2020 00:02:20

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:15', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9b480158-f9a1-44b6-8076-f201b26e8e5d' User entered '25 Sep 2020 20:02'	System	26 Sep 2020 00:02:20
	System	26 Sep 2020 00:02:20

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 6'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '12904970-b77b-4e6b-8883-23c21a598998'	System	26 Sep 2020 23:15:13
User entered 'None (1)'	System	26 Sep 2020 23:15:13

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:14:54', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '12904970-b77b-4e6b-8883-23c21a598998' User entered 'No (N)'	System	26 Sep 2020 23:15:13
	System	26 Sep 2020 23:15:13

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '12904970-b77b-4e6b-8883-23c21a598998' User entered 'No (N)'	System	26 Sep 2020 23:15:13
	System	26 Sep 2020 23:15:13

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '12904970-b77b-4e6b-8883-23c21a598998' User entered 'None (1)'	System	26 Sep 2020 23:15:13
	System	26 Sep 2020 23:15:13

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:09', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '12904970-b77b-4e6b-8883-23c21a598998'	System	26 Sep 2020 23:15:13
User entered '26 Sep 2020 19:15'	System	26 Sep 2020 23:15:13

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 7'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:22', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '32ce0812-202f-4a0a-a1d1-ebb186f784a4' User entered 'None (1)'	System	28 Sep 2020 00:03:40
	System	28 Sep 2020 00:03:40

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:25', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '32ce0812-202f-4a0a-a1d1-ebb186f784a4' User entered 'No (N)'	System	28 Sep 2020 00:03:40
	System	28 Sep 2020 00:03:40

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '32ce0812-202f-4a0a-a1d1-ebb186f784a4' User entered 'No (N)'	System	28 Sep 2020 00:03:40
	System	28 Sep 2020 00:03:40

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:30', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '32ce0812-202f-4a0a-a1d1-ebb186f784a4' User entered 'None (1)'	System	28 Sep 2020 00:03:40
	System	28 Sep 2020 00:03:40

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '32ce0812-202f-4a0a-a1d1-ebb186f784a4' User entered '27 Sep 2020 20:03'	System	28 Sep 2020 00:03:40
	System	28 Sep 2020 00:03:40

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:05', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:07', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:10', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:24', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901' User entered 'None (0)'	System	21 Sep 2020 14:00:30
	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901'	System	21 Sep 2020 14:00:30
User entered 'No (N)'	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T10:00:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '43a4a640-bff3-4337-a0f5-964e4b02f901'	System	21 Sep 2020 14:00:30
User entered '21 Sep 2020 10:00'	System	21 Sep 2020 14:00:30

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 09:45'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 12:15'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'None (0)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:54', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered 'No (N)'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-21T20:04:59', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e62d4e45-765a-461f-a196-b0fe4af0018b' User entered '21 Sep 2020 20:04'	System	22 Sep 2020 00:05:02
	System	22 Sep 2020 00:05:02

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '21 Sep 2020 13:10'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 2'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:30', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22'	System	23 Sep 2020 00:21:59
User entered 'None (0)'	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:33', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22'	System	23 Sep 2020 00:21:59
User entered 'None (0)'	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22' User entered 'None (0)'	System	23 Sep 2020 00:21:59
	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22'	System	23 Sep 2020 00:21:59
User entered 'None (0)'	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22' User entered 'None (0)'	System	23 Sep 2020 00:21:59
	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22'	System	23 Sep 2020 00:21:59
User entered 'None (0)'	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:52', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22' User entered 'No (N)'	System	23 Sep 2020 00:21:59
	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-22T20:21:54', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3ec7273e-04a3-4d69-b62f-8d9cdaf0dd22'	System	23 Sep 2020 00:21:59
User entered '22 Sep 2020 20:21'	System	23 Sep 2020 00:21:59

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 3'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:52', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:02:57', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:03:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:03:09', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'None (0)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:03:29', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered 'No (N)'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-23T20:04:03', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '84a447d1-1f02-43a2-ae45-f48329e80ece' User entered '23 Sep 2020 20:04'	System	24 Sep 2020 00:04:09
	System	24 Sep 2020 00:04:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 4'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:31:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'None (0)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:32:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered 'No (N)'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-24T20:32:06', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '75ac32a8-e91e-4942-9e2d-48216eadd18d' User entered '24 Sep 2020 20:32'	System	25 Sep 2020 00:32:09
	System	25 Sep 2020 00:32:09

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 5'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:23', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'None (0)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:25', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340' User entered 'None (0)'	System	26 Sep 2020 00:02:50
	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:28', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'None (0)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:31', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'None (0)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'None (0)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'None (0)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered 'No (N)'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-25T20:02:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '69b5ff76-56fc-43bd-87a6-506011e7f340'	System	26 Sep 2020 00:02:50
User entered '25 Sep 2020 20:02'	System	26 Sep 2020 00:02:50

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 6'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:14', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:16', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:19', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:23', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:28', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'None (0)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered 'No (N)'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-26T19:15:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '757f957c-0586-48d9-8dc3-658d00e6d71f' User entered '26 Sep 2020 19:15'	System	26 Sep 2020 23:15:47
	System	26 Sep 2020 23:15:47

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	21 Sep 2020 13:27:03
User entered 'Day 7'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:48', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'None (0)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:52', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered 'No (N)'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-09-27T20:03:55', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ca9db22b-da8d-4f8e-a4ac-a414caa63cb8' User entered '27 Sep 2020 20:03'	System	28 Sep 2020 00:03:56
	System	28 Sep 2020 00:03:56

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 13:27:03

US3412259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:35:32

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 13:27:03

US3412259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:18

US3412259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '28 Sep 2020'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:18

US3412259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:18

US3412259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:18

US3412259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Sep 2020 14:04:23

US3412259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	28 Sep 2020 14:04:23

US3412259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Oct 2020 16:38:37

US3412259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '5 Oct 2020'	Mason Urban (b) (4)	05 Oct 2020 16:38:37

US3412259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	05 Oct 2020 16:38:37

US3412259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mason Urban (b) (4)	05 Oct 2020 16:38:37

US3412259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	05 Oct 2020 16:38:43

US3412259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	05 Oct 2020 16:38:43

US3412259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Oct 2020 16:27:21

US3412259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '12 Oct 2020'	Mason Urban (b) (4)	12 Oct 2020 16:27:21

US3412259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	12 Oct 2020 16:27:21

US3412259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	Mason Urban (b) (4)	12 Oct 2020 16:27:21

US3412259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	Mason Urban (b) (4)	12 Oct 2020 16:27:28

US3412259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	12 Oct 2020 16:27:28

US3412259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:34

US3412259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:34

US3412259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:34

US3412259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'VISIT3'	System	19 Oct 2020 12:32:34

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered empty.	System	19 Oct 2020 12:32:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10

US3412259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10

US3412259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 14:19:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Oct 2020 12:33:24

US3412259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	26 Oct 2020 14:19:50
User entered '19 Oct 2020'	(b) (4), (b) (6)	19 Oct 2020 12:33:24

US3412259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:33:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:33:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered '08:15'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:33:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '19 Oct 2020 08:15'	System	19 Oct 2020 12:33:45

US3412259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 05:04:38
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Oct 2020 12:33:53

US3412259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered '1'	System	19 Oct 2020 12:33:53

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 64'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-19T21:26:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '01e753a6-b71c-4d67-a921-3658a65d0e88'	System	20 Oct 2020 01:26:25
User entered 'No (N)'	System	20 Oct 2020 01:26:25

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-19T21:26:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '01e753a6-b71c-4d67-a921-3658a65d0e88'	System	20 Oct 2020 01:26:25
User entered 'No (N)'	System	20 Oct 2020 01:26:25

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-19T21:26:20', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '01e753a6-b71c-4d67-a921-3658a65d0e88' User entered '19 Oct 2020 21:26:20'	System	20 Oct 2020 01:26:25
	System	20 Oct 2020 01:26:25

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 71'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-26T12:03:34', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '45a619a9-50eb-45ab-a669-9202135a8b2b' User entered 'No (N)'	System	26 Oct 2020 16:05:06
	System	26 Oct 2020 16:05:06

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-26T12:03:46', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '45a619a9-50eb-45ab-a669-9202135a8b2b' User entered 'No (N)'	System	26 Oct 2020 16:05:06
	System	26 Oct 2020 16:05:06

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-26T12:03:51', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '45a619a9-50eb-45ab-a669-9202135a8b2b' User entered '26 Oct 2020 12:03:51'	System	26 Oct 2020 16:05:06
	System	26 Oct 2020 16:05:06

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 78'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-31T17:00:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b1e7b74f-d37a-46ba-a2a7-be09e59a1ee8' User entered 'No (N)'	System	31 Oct 2020 21:00:46
	System	31 Oct 2020 21:00:46

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-31T17:00:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b1e7b74f-d37a-46ba-a2a7-be09e59a1ee8'	System	31 Oct 2020 21:00:46
User entered 'No (N)'	System	31 Oct 2020 21:00:46

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-10-31T17:00:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b1e7b74f-d37a-46ba-a2a7-be09e59a1ee8' User entered '31 Oct 2020 17:00:44'	System	31 Oct 2020 21:00:46
	System	31 Oct 2020 21:00:46

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered 'Day 92'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:03:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'Yes (Y)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:03:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'Yes (Y)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:03:33', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:03:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'Yes (Y)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '1'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '1'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '1'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:13', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '0'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:17', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:23', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c'	System	14 Nov 2020 22:04:35
User entered 'No (N)'	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-14T17:04:27', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8081e230-863b-4648-ad17-6c4546bc5b6c' User entered '14 Nov 2020 17:04:27'	System	14 Nov 2020 22:04:35
	System	14 Nov 2020 22:04:35

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 18:37:41

US3412259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 11:03:56
Data entry locked.	System	17 Aug 2020 18:37:41
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 18:37:41

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-25T09:10:47', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ed20d1c6-5d06-49e5-a963-2caaff43351d' User entered 'No (N)'	System	25 Nov 2020 14:10:59
	System	25 Nov 2020 14:10:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-25T09:10:53', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ed20d1c6-5d06-49e5-a963-2caaff43351d' User entered 'No (N)'	System	25 Nov 2020 14:10:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-11-25T09:10:56', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'ed20d1c6-5d06-49e5-a963-2caaff43351d' User entered '25 Nov 2020 09:10:56'	System	25 Nov 2020 14:10:59
	System	25 Nov 2020 14:10:59

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-02T07:05:11', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a00dd624-b2ee-4353-9a75-951161cef397'	System	02 Dec 2020 12:05:28
User entered 'No (N)'	System	02 Dec 2020 12:05:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-02T07:05:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a00dd624-b2ee-4353-9a75-951161cef397'	System	02 Dec 2020 12:05:28
User entered 'No (N)'	System	02 Dec 2020 12:05:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-02T07:05:26', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'a00dd624-b2ee-4353-9a75-951161cef397'	System	02 Dec 2020 12:05:28
User entered '02 Dec 2020 07:05:26'	System	02 Dec 2020 12:05:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-09T10:16:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3f11164a-c457-4c28-ae25-a6f9fb083bab' User entered 'No (N)'	System	09 Dec 2020 15:16:46
	System	09 Dec 2020 15:16:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-09T10:16:41', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3f11164a-c457-4c28-ae25-a6f9fb083bab' User entered 'No (N)'	System	09 Dec 2020 15:16:46
	System	09 Dec 2020 15:16:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-09T10:16:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3f11164a-c457-4c28-ae25-a6f9fb083bab' User entered '09 Dec 2020 10:16:44'	System	09 Dec 2020 15:16:46
	System	09 Dec 2020 15:16:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-18T05:11:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '04ca2252-b50e-45b6-9f79-66b3da413dd8'	System	18 Dec 2020 10:11:42
User entered 'No (N)'	System	18 Dec 2020 10:11:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-18T05:11:32', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '04ca2252-b50e-45b6-9f79-66b3da413dd8'	System	18 Dec 2020 10:11:42
User entered 'No (N)'	System	18 Dec 2020 10:11:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-18T05:11:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '04ca2252-b50e-45b6-9f79-66b3da413dd8' User entered '18 Dec 2020 05:11:37'	System	18 Dec 2020 10:11:42
	System	18 Dec 2020 10:11:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-26T09:40:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9d590ff9-a096-4fd2-b80e-39988956ad98'	System	26 Dec 2020 14:41:22
User entered 'No (N)'	System	26 Dec 2020 14:41:22

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-26T09:41:12', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9d590ff9-a096-4fd2-b80e-39988956ad98' User entered 'No (N)'	System	26 Dec 2020 14:41:22
	System	26 Dec 2020 14:41:22

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-26T09:41:18', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '9d590ff9-a096-4fd2-b80e-39988956ad98' User entered '26 Dec 2020 09:41:18'	System	26 Dec 2020 14:41:22
	System	26 Dec 2020 14:41:22

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-30T05:26:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '273a4142-1665-485d-9bed-77fb6db08865' User entered 'No (N)'	System	30 Dec 2020 10:27:14
	System	30 Dec 2020 10:27:14

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-30T05:27:01', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '273a4142-1665-485d-9bed-77fb6db08865'	System	30 Dec 2020 10:27:14
User entered 'No (N)'	System	30 Dec 2020 10:27:14

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2020-12-30T05:27:10', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '273a4142-1665-485d-9bed-77fb6db08865' User entered '30 Dec 2020 05:27:10'	System	30 Dec 2020 10:27:14
	System	30 Dec 2020 10:27:14

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-06T07:57:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8f221332-13ec-4fd0-997b-e4efd005e4dd' User entered 'No (N)'	System	06 Jan 2021 12:57:48
	System	06 Jan 2021 12:57:48

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-06T07:57:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8f221332-13ec-4fd0-997b-e4efd005e4dd'	System	06 Jan 2021 12:57:48
User entered 'No (N)'	System	06 Jan 2021 12:57:48

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-06T07:57:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8f221332-13ec-4fd0-997b-e4efd005e4dd' User entered '06 Jan 2021 07:57:44'	System	06 Jan 2021 12:57:48
	System	06 Jan 2021 12:57:48

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-14T18:06:58', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7436c530-960e-469c-868a-635a82914d78'	System	14 Jan 2021 23:07:09
User entered 'No (N)'	System	14 Jan 2021 23:07:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-14T18:07:01', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7436c530-960e-469c-868a-635a82914d78'	System	14 Jan 2021 23:07:09
User entered 'No (N)'	System	14 Jan 2021 23:07:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-14T18:07:04', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '7436c530-960e-469c-868a-635a82914d78'	System	14 Jan 2021 23:07:09
User entered '14 Jan 2021 18:07:04'	System	14 Jan 2021 23:07:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-21T06:49:43', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'fe1c76ff-1b9c-4abb-9759-f3f19182f457'	System	24 Jan 2021 20:55:35
User entered 'No (N)'	System	24 Jan 2021 20:55:35

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-21T06:49:45', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'fe1c76ff-1b9c-4abb-9759-f3f19182f457' User entered 'No (N)'	System	24 Jan 2021 20:55:35
	System	24 Jan 2021 20:55:35

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-21T06:49:50', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'fe1c76ff-1b9c-4abb-9759-f3f19182f457'	System	24 Jan 2021 20:55:35
User entered '21 Jan 2021 06:49:50'	System	24 Jan 2021 20:55:35

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-29T01:35:19', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd74550b9-6e6c-4853-aff7-257201ae8888'	System	29 Jan 2021 06:35:28
User entered 'No (N)'	System	29 Jan 2021 06:35:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-29T01:35:21', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd74550b9-6e6c-4853-aff7-257201ae8888'	System	29 Jan 2021 06:35:28
User entered 'No (N)'	System	29 Jan 2021 06:35:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-01-29T01:35:25', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'd74550b9-6e6c-4853-aff7-257201ae8888' User entered '29 Jan 2021 01:35:25'	System	29 Jan 2021 06:35:28
	System	29 Jan 2021 06:35:28

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-04T07:33:33', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '46b176ec-2c52-4a7b-bb73-66a4270cb3d9' User entered 'No (N)'	System	04 Feb 2021 12:33:42
	System	04 Feb 2021 12:33:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-04T07:33:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '46b176ec-2c52-4a7b-bb73-66a4270cb3d9'	System	04 Feb 2021 12:33:42
User entered 'No (N)'	System	04 Feb 2021 12:33:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-04T07:33:38', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '46b176ec-2c52-4a7b-bb73-66a4270cb3d9' User entered '04 Feb 2021 07:33:38'	System	04 Feb 2021 12:33:42
	System	04 Feb 2021 12:33:42

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-10T20:41:35', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e6c4ad5b-1040-4274-bb28-706745389a2c' User entered 'No (N)'	System	11 Feb 2021 01:41:46
	System	11 Feb 2021 01:41:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-10T20:41:36', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e6c4ad5b-1040-4274-bb28-706745389a2c' User entered 'No (N)'	System	11 Feb 2021 01:41:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-10T20:41:40', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'e6c4ad5b-1040-4274-bb28-706745389a2c' User entered '10 Feb 2021 20:41:40'	System	11 Feb 2021 01:41:46
	System	11 Feb 2021 01:41:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-17T00:38:37', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'db5ad66a-da89-4081-a3c2-c1b5a07887df' User entered 'No (N)'	System	17 Feb 2021 05:38:46
	System	17 Feb 2021 05:38:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-17T00:38:39', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'db5ad66a-da89-4081-a3c2-c1b5a07887df' User entered 'No (N)'	System	17 Feb 2021 05:38:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-17T00:38:44', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'db5ad66a-da89-4081-a3c2-c1b5a07887df' User entered '17 Feb 2021 00:38:44'	System	17 Feb 2021 05:38:46
	System	17 Feb 2021 05:38:46

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-24T03:49:18-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '64269615-f6eb-4357-ae28-bf7dbe1d654d' User entered 'No (N)'	System	24 Feb 2021 08:49:27
	System	24 Feb 2021 08:49:27

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-24T03:49:20-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '64269615-f6eb-4357-ae28-bf7dbe1d654d' User entered 'No (N)'	System	24 Feb 2021 08:49:27
	System	24 Feb 2021 08:49:27

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-02-24T03:49:23-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '64269615-f6eb-4357-ae28-bf7dbe1d654d' User entered '24 Feb 2021 08:49:23'	System	24 Feb 2021 08:49:27
	System	24 Feb 2021 08:49:27

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-03T07:57:22-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '40003e92-175c-47c2-8fae-3023518dea9f'	System	03 Mar 2021 12:57:31
User entered 'No (N)'	System	03 Mar 2021 12:57:31

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-03T07:57:24-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '40003e92-175c-47c2-8fae-3023518dea9f'	System	03 Mar 2021 12:57:31
User entered 'No (N)'	System	03 Mar 2021 12:57:31

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-03T07:57:28-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '40003e92-175c-47c2-8fae-3023518dea9f' User entered '03 Mar 2021 07:57:28'	System	03 Mar 2021 12:57:31
	System	03 Mar 2021 12:57:31

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-10T07:48:48-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b5c080c6-fba9-4814-b5ca-cfa1c0c289fc'	System	10 Mar 2021 12:48:57
User entered 'No (N)'	System	10 Mar 2021 12:48:57

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-10T07:48:50-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b5c080c6-fba9-4814-b5ca-cfa1c0c289fc'	System	10 Mar 2021 12:48:57
User entered 'No (N)'	System	10 Mar 2021 12:48:57

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-10T07:48:53-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b5c080c6-fba9-4814-b5ca-cfa1c0c289fc' User entered '10 Mar 2021 07:48:53'	System	10 Mar 2021 12:48:57
	System	10 Mar 2021 12:48:57

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-17T16:55:56-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f6fba6d5-53cf-4be4-9ec1-9f961d20dd0d'	System	17 Mar 2021 20:56:09
User entered 'No (N)'	System	17 Mar 2021 20:56:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-17T16:55:58-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f6fba6d5-53cf-4be4-9ec1-9f961d20dd0d'	System	17 Mar 2021 20:56:09
User entered 'No (N)'	System	17 Mar 2021 20:56:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-17T16:56:01-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'f6fba6d5-53cf-4be4-9ec1-9f961d20dd0d' User entered '17 Mar 2021 16:56:01'	System	17 Mar 2021 20:56:09
	System	17 Mar 2021 20:56:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-24T06:11:43-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '589cb8fb-f72a-4c7b-bed2-3145a0d1e01a' User entered 'No (N)'	System	24 Mar 2021 10:11:54
	System	24 Mar 2021 10:11:54

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-24T06:11:46-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '589cb8fb-f72a-4c7b-bed2-3145a0d1e01a' User entered 'No (N)'	System	24 Mar 2021 10:11:54
	System	24 Mar 2021 10:11:54

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-24T06:11:49-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '589cb8fb-f72a-4c7b-bed2-3145a0d1e01a' User entered '24 Mar 2021 06:11:49'	System	24 Mar 2021 10:11:54
	System	24 Mar 2021 10:11:54

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-31T05:58:01-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '211e74ee-9e5c-45e7-8e4d-2d970ff9e8e3'	System	31 Mar 2021 09:58:09
User entered 'No (N)'	System	31 Mar 2021 09:58:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-31T05:58:03-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '211e74ee-9e5c-45e7-8e4d-2d970ff9e8e3'	System	31 Mar 2021 09:58:09
User entered 'No (N)'	System	31 Mar 2021 09:58:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-31T05:58:06-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '211e74ee-9e5c-45e7-8e4d-2d970ff9e8e3'	System	31 Mar 2021 09:58:09
User entered '31 Mar 2021 05:58:06'	System	31 Mar 2021 09:58:09

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-07T06:53:42-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b362837b-b80d-4feb-95d5-9fefb9d639b9'	System	07 Apr 2021 10:53:53
User entered 'No (N)'	System	07 Apr 2021 10:53:53

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-07T06:53:43-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b362837b-b80d-4feb-95d5-9fefb9d639b9'	System	07 Apr 2021 10:53:53
User entered 'No (N)'	System	07 Apr 2021 10:53:53

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-07T06:53:50-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'b362837b-b80d-4feb-95d5-9fefb9d639b9'	System	07 Apr 2021 10:53:53
User entered '07 Apr 2021 06:53:50'	System	07 Apr 2021 10:53:53

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-14T06:06:11-06:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4bba48fb-0e5c-4441-8aca-31dbf094dc4d'	System	14 Apr 2021 12:06:18
User entered 'No (N)'	System	14 Apr 2021 12:06:18

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-14T06:06:13-06:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4bba48fb-0e5c-4441-8aca-31dbf094dc4d'	System	14 Apr 2021 12:06:18
User entered 'No (N)'	System	14 Apr 2021 12:06:18

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-14T06:06:15-06:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '4bba48fb-0e5c-4441-8aca-31dbf094dc4d'	System	14 Apr 2021 12:06:18
User entered '14 Apr 2021 06:06:15'	System	14 Apr 2021 12:06:18

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-24T10:00:42-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3578b3a3-48a8-46f5-abe4-a54ae5f44190'	System	24 Apr 2021 14:00:49
User entered 'No (N)'	System	24 Apr 2021 14:00:49

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-24T10:00:43-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3578b3a3-48a8-46f5-abe4-a54ae5f44190'	System	24 Apr 2021 14:00:49
User entered 'No (N)'	System	24 Apr 2021 14:00:49

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-24T10:00:46-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '3578b3a3-48a8-46f5-abe4-a54ae5f44190'	System	24 Apr 2021 14:00:49
User entered '24 Apr 2021 10:00:46'	System	24 Apr 2021 14:00:49

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-30T06:52:57-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8d94f50e-c8f9-4998-9d2d-49153fdc0e69'	System	30 Apr 2021 10:53:07
User entered 'No (N)'	System	30 Apr 2021 10:53:07

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Have you been exposed to someone with 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 (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-30T06:52:59-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8d94f50e-c8f9-4998-9d2d-49153fdc0e69'	System	30 Apr 2021 10:53:07
User entered 'No (N)'	System	30 Apr 2021 10:53:07

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-04-30T06:53:02-04:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: '8d94f50e-c8f9-4998-9d2d-49153fdc0e69' User entered '30 Apr 2021 06:53:02'	System	30 Apr 2021 10:53:07
	System	30 Apr 2021 10:53:07

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 09:24:39

US3412259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:35:32

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 09:24:39
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 09:24:39

US3412259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:32

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 00:44:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-03T15:26:01-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'fc615fc9-1585-4d06-b9b2-7af1881c5298'	System	03 Mar 2021 20:26:08
User entered 'No (N)'	System	03 Mar 2021 20:26:08

US3412259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:35:32

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 00:44:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2180EDE8-8589-4405-AFAB-280857B01F26)', Time: '2021-03-03T15:26:05-05:00', User OID: 'PatientReportedOutcome (US3412259)', ODM File OID: 'fc615fc9-1585-4d06-b9b2-7af1881c5298'	System	03 Mar 2021 20:26:08
User entered '03 Mar 2021 15:26:05'	System	03 Mar 2021 20:26:08

US3412259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User closed query 'Please update to Not Done since subject was in illness phase during this time.' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 16:19:26
DataPoint Verified.		15 Dec 2020 16:19:11
User closed query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Dec 2020 14:49:29
Query 'Please update to Not Done since subject was in illness phase during this time.' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	02 Dec 2020 14:49:22
User opened query 'Was Contact Attempted? = No and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is provided. Please review and reconcile.' (Site from System).	System	02 Dec 2020 14:49:12
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 14:49:12
User opened query 'Please update to Not Done since subject was in illness phase during this time.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 14:12:03
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Nov 2020 19:20:51

US3412259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:19:11
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 14:49:12
User entered '17 Nov 2020'	Mason Urban (b) (4)	17 Nov 2020 19:20:51

US3412259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:19:11
User entered empty; reason for change Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 14:49:29
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 14:49:12
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Nov 2020 19:20:51

US3412259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:19:11
User entered 'subject was in illness phase during this time' reason for change: Data Entry Error	Jacob sekinger (b) (4)	02 Dec 2020 14:49:12
User entered empty.	Mason Urban (b) (4)	17 Nov 2020 19:20:51

US3412259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Nov 2020 19:17:43

US3412259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:16:10
User entered 'I'	System	17 Nov 2020 19:17:43

US3412259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Dec 2020 15:48:34

US3412259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '21 Dec 2020'	Mason Urban (b) (4)	21 Dec 2020 15:48:34

US3412259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	21 Dec 2020 15:48:34

US3412259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Mason Urban (b) (4)	21 Dec 2020 15:48:34

US3412259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	21 Dec 2020 15:48:48

US3412259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User entered 'I'	System	21 Dec 2020 15:48:48

US3412259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'No (N)'	Mason Urban (b) (4)	18 Feb 2021 17:16:44

US3412259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 17:16:44

US3412259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 17:16:44

US3412259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'PATIENT NOT CALLED DUE TO SITE ERROR. SITE STAFF INSTRUCTED TO COMPLETE REGULAR SAFETY CALLS ALONGSIDE OPEN LABEL PHASE'	Mason Urban (b) (4)	18 Feb 2021 17:16:44

US3412259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 17:15:45

US3412259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User entered 'I'	System	18 Feb 2021 17:15:45

US3412259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 17:15:56

US3412259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '18 Feb 2021'	Mason Urban (b) (4)	18 Feb 2021 17:15:56

US3412259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	18 Feb 2021 17:15:56

US3412259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered empty.	Mason Urban (b) (4)	18 Feb 2021 17:15:56

US3412259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Feb 2021 17:16:00

US3412259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:41:14
User entered 'I'	System	18 Feb 2021 17:16:00

US3412259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:38

US3412259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:38

US3412259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[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 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:38

US3412259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered 'VISIT4'	System	25 Mar 2021 13:02:38

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '08:14'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered '25 Mar 2021 08:14'	System	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '64'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered 'bpm'	System	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '14'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered 'breaths/min'	System	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '132'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered 'mmHg'	System	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '82'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User entered 'mmHg'	System	31 Mar 2021 18:44:09

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41

US3412259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41

US3412259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:50

US3412259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:02:50

US3412259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:19

US3412259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:19

US3412259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered '08:25'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:19

US3412259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered '25 Mar 2021 08:25'	System	25 Mar 2021 13:03:19

US3412259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:57:10
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:25

US3412259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:04:29
User entered 'I'	System	25 Mar 2021 13:03:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:32

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Please reconcile and enter the following missing pages that are required: Severity page, Illness Day 1 date, vitals, PE, blood, Saliva, AE of COVID' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 13:40:45
Query 'Please reconcile and enter the following missing pages that are required: Severity page, Illness Day 1 date, vitals, PE, blood, Saliva, AE of COVID' answered with 'updated all pages' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 17:44:15
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:42:41
User opened query 'Please reconcile and enter the following missing pages that are required: Severity page, Illness Day 1 date, vitals, PE, blood, Saliva, AE of COVID' (Site from CRA).		15 Nov 2020 22:29:39
User entered '09 Nov 2020'		12 Nov 2020 21:24:15

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:32

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:42:41
User entered '13:00'		12 Nov 2020 21:24:15

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:32

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:41
User entered '09 Nov 2020 13:00'	System	12 Nov 2020 21:24:15

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:32

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:42:41
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'		12 Nov 2020 21:24:15

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:35:32

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:41
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:42:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:24:15

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '03 Nov 2020'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 19:54:03
DataPoint Un-verified.		28 Jan 2021 19:53:55
DataPoint Verified.		28 Jan 2021 19:53:50
User closed query 'Please confirm whether assessment was done and update as appropriate' (Site from CRA).		28 Jan 2021 19:53:47
User closed query 'Per CDM: It appears that Assessment Not Done is checked yet data is present from Day 1 to Day 6. Please reconcile and update accordingly' (Site from DM).		18 Jan 2021 11:49:41
Query 'Please confirm whether assessment was done and update as appropriate' answered with 'ASSESSMENT WAS DONE' (Site from CRA).	Melissa Fuson (b) (4)	14 Jan 2021 16:07:09
User opened query 'Please confirm whether assessment was done and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:55:45
Query 'Per CDM: It appears that Assessment Not Done is checked yet data is present from Day 1 to Day 6. Please reconcile and update accordingly' answered with 'UPDATED TO NOT DONE' (Site from DM).	Melissa Fuson (b) (4)	14 Jan 2021 15:43:05
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
User opened query 'Per CDM: It appears that Assessment Not Done is checked yet data is present from Day 1 to Day 6. Please reconcile and update accordingly' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 07:35:41
DataPoint Verified.		17 Nov 2020 15:44:02

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Please clarify what NF means' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 19:54:10
DataPoint Verified.		28 Jan 2021 19:54:08
Query 'Please clarify what NF means' answered with 'TYPO ERROR UPDATED TO ND' (Site from CRA).	Melissa Fuson (b) (4)	14 Jan 2021 16:07:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Melissa Fuson (b) (4)	14 Jan 2021 16:06:55
User opened query 'Please clarify what NF means' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 15:55:28
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
User entered 'NF' (non-conformant).	Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 16:06:55
User entered empty.	System	12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:55:30
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:42:51
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:26:31

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 2 (Day 2)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '04 Nov 2020'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:17
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:20
User entered '0' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '1'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:19
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:43:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:43:20
User entered empty.	System	12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:20
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:27:40

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 3 (Day 3)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '05 Nov 2020'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:25
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:34
User entered '0' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '1'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:27
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:43:34
User entered empty.	System	12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:28
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:34
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:43:34
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:31:47

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 4 (Day 4)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '06 Nov 2020'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:39
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:48
User entered '0' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '1'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:41
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:43:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:43:48
User entered empty.	System	12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:43
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:43:48
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:43:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		12 Nov 2020 21:32:37

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered '07 Nov 2020'	(b) (4), (b) (6)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:49
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:03
User entered '0' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:44:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '1' reason for change: Data Entry Error	(b) (4)	13 Nov 2020 14:17:17
User entered '0'	(b) (4)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:51
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:44:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:44:03
User entered empty.	System	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:52
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:03
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:44:03
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:16:22

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '08 Nov 2020'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:56:58
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:20
User entered '0' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:44:20
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '1'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:57:00
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:44:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:44:20
User entered empty.	System	13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:57:02
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:20
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Jan 2021 15:44:20
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:17:17

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '09 Nov 2020'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '0'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:57:09
DataPoint Un-verified.	Melissa Fuson (b) (4)	14 Jan 2021 15:44:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Melissa Fuson (b) (4)	14 Jan 2021 15:44:31
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	14 Jan 2021 15:44:31
User entered empty.	System	13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered '36.8' C	(b) (4), (b) (6)	13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'mild per source? Please confirm and update accordingly' (Site from CRA).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:57:23
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:48:22
Query 'mild per source? Please confirm and update accordingly' answered with 'UPDATED TO MILD PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:09:24
User entered 'Mild (Mild)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:09:07
User opened query 'mild per source? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:48:22
DataPoint Un-verified.		17 Nov 2020 15:47:52
DataPoint Verified.		17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 14:19:51

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '10 Nov 2020'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '0'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '99'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '97.2' F		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:21:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 9 (Day 9)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '11 Nov 2020'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '0'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered '93'	(b) (4), (b) (6)	13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered '96.4' F	(b) (4), (b) (6)	13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:22:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 10 (Day 10)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '12 Nov 2020'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '0'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '91'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '97.1' F		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'None per source? Please confirm and update' (Site from CRA).	(b) (4)	18 Nov 2020 20:00:59
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:48:22
Query 'None per source? Please confirm and update' answered with 'updated and confirmed per source' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 17:36:53
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 17:36:20
User opened query 'None per source? Please confirm and update' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:51:44
DataPoint Un-verified.		17 Nov 2020 15:51:18
DataPoint Verified.		17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'None per source? Please confirm and update' (Site from CRA).	(b) (4)	18 Nov 2020 20:01:02
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:48:22
Query 'None per source? Please confirm and update' answered with 'updated and confirmed per source' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 17:37:00
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	17 Nov 2020 17:36:20
User opened query 'None per source? Please confirm and update' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 15:57:16
DataPoint Un-verified.		17 Nov 2020 15:51:21
DataPoint Verified.		17 Nov 2020 15:44:02
User entered empty.		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 14:23:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 11 (Day 11)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '13 Nov 2020'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '0'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '99'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered '99.1' F		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'	(b) (4), (b) (6)	13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Moderate (Moderate)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'Mild (Mild)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	17 Nov 2020 15:44:02
User entered 'None (None)'	(b) (4), (b) (6)	13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:44:02
User entered 'None (None)'		13 Nov 2020 18:45:04

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 12 (Day 12)'	Melissa Fuson (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '14 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '98'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '96.3' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:13:08

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 13 (Day 13)'	Melissa Fuson (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '15 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '99'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '97.0' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:14:48

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 14 (Day 14)'	Melissa Fuson (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '16 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '98'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '97.1' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:16:26

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 15 (Day 15)'	Melissa Fuson (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '17 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '95'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered '97.4' F	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:48:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 21:46:12

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 16 (Day 16)'	Melissa Fuson (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:02
User entered '18 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:03
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:15:59
User entered '98'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:01
User entered '97.1' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:09
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:11
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:15
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:17
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:23
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:27
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:16:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:07:45

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 17 (Day 17)'	Melissa Fuson (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:06
User entered '19 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:08
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:10
User entered '96'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:14
User entered '97.4' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:16
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 22:17:48
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:10:21

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 18 (Day 18)' reason for change:	(b) (4)	
Data Entry Error	Melissa Fuson (b) (4)	23 Nov 2020 17:12:48
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	23 Nov 2020 17:12:25
	(b) (4)	

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:40
User entered '20 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:45:35
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:42
User entered '95'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:45
User entered '96.1' F	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:47
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:54
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:58
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:38:59
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'None per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 21:28:43
DataPoint Verified.		24 Nov 2020 21:28:41
Query 'None per source. Please confirm and update as appropriate' answered with 'none' (Site from CRA).	Steven Anderson (b) (4)	24 Nov 2020 21:12:14
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 21:12:10
User opened query 'None per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:37:35
User entered 'Not Done (Not Done)'	Melissa Fuson (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:29
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:31
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (18)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:39:40
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:12:25

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 19 (Day 19)'	Melissa Fuson (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:42
User entered '21 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:44
User entered '0'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:45
User entered '98'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:47
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 17:16:33
User entered '97.1' F reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:16:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	23 Nov 2020 17:14:38
User entered '97.1' (non-conformant).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:49
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:50
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:52
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:53
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:55
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:40:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:26
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (19)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:41:34
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:14:38

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Day 20 (Day 20)'	Melissa Fuson (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:14
User entered '22 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:45:51
User entered '0'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:16
User entered '95'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User entered '%'	System	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:17
User entered '97.1' F	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:19
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:20
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:22
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:24
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:25
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:27
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:28
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:30
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:32
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:33
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:35
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:37
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:39
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:43
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Symptom Log (20)

Generated On: 11 Aug 2021 22:35:32

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:48
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 16:42:45
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	24 Nov 2020 13:38:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered '09 Nov 2020'		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered 'Yes (Y)'		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Please update as samples and information become available ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:46:09
Query 'Please update as samples and information become available ' answered with 'WILL NOTE ON FOLDER AS SAMPLES AND INFORMATION BECOME AVAILABLE TO FILL OUT SALIVA COLLECTION LOG' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 14:43:40
User opened query 'Please update as samples and information become available ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 14:37:37
User closed query 'Please complete saliva collection CRF' (Site from CRA).		19 Nov 2020 14:37:37
Query 'Please complete saliva collection CRF' answered with 'SALIVA COLLECTED THIS DAY WAS FOR ILLNESS VISIT ON 09-NOV-2020. WE DO NOT HAVE DATA FOR REST OF VISITS YET IN SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 14:35:53
User opened query 'Please complete saliva collection CRF' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 20:01:56
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).		18 Nov 2020 10:18:17
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 'updated ae ' (Site from System).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:42:32
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:07:00
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	12 Nov 2020 21:24:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered '09 Nov 2020'		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered empty.		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered 'No (N)'		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered empty.		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 16:07:00
User entered empty.		12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 22:35:32

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:15:55
User entered 'I'	System	12 Nov 2020 21:24:46

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Did the subject have Respiratory Rates \$\geq\$ 30 per Minute?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Did the subject have Heart Rate \$\geq\$ 125 beats per minute](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Heart Rate](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

Did the subject have Oxygen Saturation of SpO2 ≤ 93% on room air at sea level?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'No update - please update fields below' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
User closed query 'Please complete the start date, end date, and oxygen saturation sections below this one' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:46:55
Query 'No update - please update fields below' answered with 'this has been updated with subjects lowest O2 documentation' (Site from CRA).	Steven Anderson (b) (4)	20 Nov 2020 16:44:44
Query 'Please complete the start date, end date, and oxygen saturation sections below this one' answered with 'this has been updated with subjects lowest O2 documentation' (Site from CRA).	Steven Anderson (b) (4)	20 Nov 2020 16:44:41
User opened query 'No update - please update fields below' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:33:34
User closed query 'Please reconcile as symptom log notes the first SpO2 of 93% on 11Nov20 and last value 93 or below was on 12Nov20' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:33:34
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:32:55
User opened query 'Please complete the start date, end date, and oxygen saturation sections below this one' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:43:10
Query 'Please reconcile as symptom log notes the first SpO2 of 93% on 11Nov20 and last value 93 or below was on 12Nov20' answered with 'UPDATED FROM SYMPTOM LOG RECORDINGS' (Site from CRA).	Melissa Fuson (b) (4)	19 Nov 2020 14:38:03
DataPoint Un-verified.	Melissa Fuson (b) (4)	19 Nov 2020 14:37:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 14:37:35
User opened query 'Please reconcile as symptom log notes the first SpO2 of 93% on 11Nov20 and last value 93 or below was on 12Nov20' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:42:16

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

Audit	User	Time (GMT)
Query 'Please reconcile as symptom log notes the first SpO2 of \leq 93 = 11Nov2020 with 93%' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:41:14
User opened query 'Please reconcile as symptom log notes the first SpO2 of \leq 93 = 11Nov2020 with 93%' (Site from CRA).		19 Nov 2020 03:22:53
DataPoint Verified.		18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Start Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Please reconcile as first value was on 11Nov2020' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 16:44:33
DataPoint Verified.		24 Nov 2020 16:44:28
Query 'Please reconcile as first value was on 11Nov2020' answered with 'updated date' (Site from CRA).	Melissa Fuson (b) (4)	24 Nov 2020 13:33:30
User entered '11 Nov 2020' reason for change: Data Entry Error	(b) (4)	24 Nov 2020 13:33:11
User opened query 'Please reconcile as first value was on 11Nov2020' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:46:41
User entered '12 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Nov 2020 16:44:16
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:28
DataPoint Verified.		18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:24:56
User entered '12 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Nov 2020 16:44:16
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 18:34:29
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Oxygen Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 03:24:59
User entered '91' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Nov 2020 16:44:16
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 18:34:31
DataPoint Verified.		18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[PaO2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:35:32

[Did the subject have Respiratory failure?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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[Start Date](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Did the subject have Acute Respiratory Distress Syndrome \(ARDS\)?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[High-Flow Oxygen?](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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[End Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:35:32

[Non-Invasive Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
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US3412259

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:34:09

US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Mechanical Ventilation?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
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US3412259

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
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US3412259

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US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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Generated On: 11 Aug 2021 22:35:32

[ECMO?](#)

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DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:03
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US3412259

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US3412259

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Generated On: 11 Aug 2021 22:35:32

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

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
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US3412259

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US3412259

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US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 22:35:32

[Evidence of Shock Requires
Vasopressors](#)

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US3412259

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US3412259

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Generated On: 11 Aug 2021 22:35:32

[Acute Renal Dysfunction?](#)

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US3412259

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US3412259

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[Hepatic Dysfunction?](#)

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US3412259

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US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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[Neurologic Dysfunction?](#)

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US3412259

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[Clinical Evidence](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
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US3412259

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US3412259

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[Radiographical Evidence](#)

Audit	User	Time (GMT)
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US3412259

Folder: Covid-19 Assessment 09 Nov 2020

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[Admission to an intensive care unit due to SARS-CoV-2](#)

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Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:04
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US3412259

Folder: Covid-19 Assessment 09 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:35:32

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 01:16:09
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:44:12
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:17:02

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Per GCL Lab Recon: Saliva: Please confirm the visit days and date of collection, as PPD lab has Visit day 3-21 dated 03DEC2020, if its incorrect kindly verify if it can be updated via DCF. Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	14 Apr 2021 04:55:05
Query 'Per GCL Lab Recon: Saliva: Please confirm the visit days and date of collection, as PPD lab has Visit day 3-21 dated 03DEC2020, if its incorrect kindly verify if it can be updated via DCF. Thanks ' answered with 'edc is correct will update with ppd' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	07 Apr 2021 18:52:39
User opened query 'Per GCL Lab Recon: Saliva: Please confirm the visit days and date of collection, as PPD lab has Visit day 3-21 dated 03DEC2020, if its incorrect kindly verify if it can be updated via DCF. Thanks ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 07:20:42
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 13:52:05
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11,13,15,17,22NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Dec 2020 20:02:28
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11,13,15,17,22NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SALIVIA WAS SHIPPED. PPD ACCESSION NUMBER: 1F69153' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 18:02:41
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 11,13,15,17,22NOV2020 is recorded under Illness Visit Day 3,5,7,9,14 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 07:06:16
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 13:52:07
User entered '11 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:52:10
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 13:52:37
User entered '13 Nov 2020'	Steven Anderson (b) (4)	20 Nov 2020 16:41:28
	(b) (4)	

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:52:44
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:52:46
User entered '15 Nov 2020'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 13:52:50
User entered 'Yes (Y)'	Steven Anderson (b) (4)	20 Nov 2020 16:41:28
	(b) (4)	

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 13:52:52
User entered '17 Nov 2020'	Steven Anderson (b) (4)	20 Nov 2020 16:41:28
	(b) (4)	

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:32

Was Saliva Collected?

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	02 Dec 2020 13:52:59
User closed query 'Data is required. Please complete.' (Site from System).	System	24 Nov 2020 20:23:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Nov 2020 20:23:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 20:23:49
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:41:28
User entered empty.	Steven Anderson (b) (4)	20 Nov 2020 16:41:28
	(b) (4)	

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:53:00
User entered '22 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	24 Nov 2020 20:23:49
User entered empty.	Steven Anderson (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 16:27:52
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 21:04:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 21:04:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Dec 2020 21:04:48
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:41:28
User entered empty.	Steven Anderson (b) (4)	20 Nov 2020 16:41:28
	(b) (4)	

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:27:54
User entered '29 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 21:04:48
User entered empty.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:32

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:32

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 16:00:24
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Dec 2020 21:05:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Dec 2020 21:05:12
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 21:05:12
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Nov 2020 16:41:28
User entered empty.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Please confirm date of collection for this sample' (Site from CRA).	(b) (4), (b) (6)	14 Jan 2021 16:00:25
DataPoint Verified.		14 Jan 2021 16:00:22
Query 'Please confirm date of collection for this sample' answered with 'DATA ENTRY ERROR SHOULD HAVE BEEN 03-DEC-2020' (Site from CRA).	Melissa Fuson (b) (4)	30 Dec 2020 14:59:39
User entered '03 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	30 Dec 2020 14:59:11
User opened query 'Please confirm date of collection for this sample' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 16:28:13
User entered '03 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Dec 2020 21:05:12
User entered empty.	Steven Anderson (b) (4)	20 Nov 2020 16:41:28

US3412259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Re-query: Please verify previous query response as saliva is to be returned to the site within 24 hrs of collection. there should be at least 3 samples that should have been returned to the site at this time' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 17:49:41
Query 'Re-query: Please verify previous query response as saliva is to be returned to the site within 24 hrs of collection. there should be at least 3 samples that should have been returned to the site at this time' answered with 'SALIVA DAYS HAVE BEEN UPDATED' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	23 Nov 2020 17:05:34
User opened query 'Re-query: Please verify previous query response as saliva is to be returned to the site within 24 hrs of collection. there should be at least 3 samples that should have been returned to the site at this time' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:34:08
User closed query 'Please reconcile and enter saliva log as required' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 04:34:08
Query 'Please reconcile and enter saliva log as required' answered with 'INFORMATION NOT AVAILABE YET. WILL UPDATE AS IT COMES IN.' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 14:44:39
User opened query 'Please reconcile and enter saliva log as required' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 13:40:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:29:49
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:29:49
User entered '9 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:29:49
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered 'SICKD1'	System	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '9 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '13:23'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered '9 Nov 2020 13:23'	System	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '164.0' cm	Melissa Fuson (b) (4)	17 Nov 2020 17:20:55
DataPoint set to visible.	(b) (4) System	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '69.5' kg	Melissa Fuson (b) (4)	17 Nov 2020 17:20:55
DataPoint set to visible.	(b) (4) System	17 Nov 2020 17:19:05

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '36.8' C	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '88'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered 'bpm'	System	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '18'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered 'breaths/min'	System	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '128'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered 'mmHg'	System	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:24
User entered '89'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User entered 'mmHg'	System	17 Nov 2020 17:20:55

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34

US3412259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34

US3412259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:40
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:21:15

US3412259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:40
User entered '9 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:21:15

US3412259

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:35:32

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:53
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:21:29

US3412259

Folder: Illness Visit Day 1 (1)

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

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:50:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:31:53
User entered '9 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:21:29

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:09
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:09
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered 'SICKD28'	System	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '09:11'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered '3 Dec 2020 09:11'	System	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '163.0' cm	Melissa Fuson (b) (4)	03 Dec 2020 15:50:48
DataPoint set to visible.	(b) (4) System	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '69.3' kg	Melissa Fuson (b) (4)	03 Dec 2020 15:50:48
DataPoint set to visible.	(b) (4) System	03 Dec 2020 15:49:27

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '36.6' C	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered 'Oral (Oral)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered empty.	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '74'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered 'bpm'	System	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '15'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered 'breaths/min'	System	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '108'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered 'mmHg'	System	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:35
User entered '72'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User entered 'mmHg'	System	03 Dec 2020 15:50:48

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:46
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:51:10

US3412259

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:26:46
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:51:10

US3412259

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:35:32

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:27:17
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:51:25

US3412259

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 11 Aug 2021 22:35:32

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 00:15:26
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:27:17
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:51:25

US3412259

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:55:51

US3412259

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:55:51

US3412259

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	20 Jan 2021 14:55:51

US3412259

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

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 14:55:51

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 12:04:56
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:54:11

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Apr 2021 06:18:08
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:04:58
User entered 'Amendment 6 or later (Amendment 6 or later)'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 12:04:56
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 18:39:11
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:54:11

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Placebo (Placebo)'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '1'	System	20 Jan 2021 14:56:04

US3412259

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

Form: Unblinding

Generated On: 11 Aug 2021 22:35:32

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	20 Jan 2021 14:56:04

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '163.5' cm	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '68.3' kg	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25.54966'	System	20 Jan 2021 14:58:07
DataPoint set to visible.	System	20 Jan 2021 14:56:04

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '163.5' cm	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '68.3' kg	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25.54966'	System	20 Jan 2021 14:58:07
DataPoint set to visible.	System	20 Jan 2021 14:56:04

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User accepted default value 'Pre-Dose (PREDOSE)'	Mason Urban (b) (4) (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '8:57'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '18 Jan 2021 8:57'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '36.6' C	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Oral (Oral)'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '60'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'bpm'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '12'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'breaths/min'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '132'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '82'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '163.5' cm	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '68.3' kg	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:35:32

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25.54966'	System	20 Jan 2021 14:58:07
DataPoint set to visible.	System	20 Jan 2021 14:56:04

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User accepted default value 'Post-Dose (POSTDOSE)'	Mason Urban (b) (4) (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '9:40'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '18 Jan 2021 9:40'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '97.6' F	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Oral (Oral)'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '66'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'bpm'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '13'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'breaths/min'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '122'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '78'	Mason Urban (b) (4)	20 Jan 2021 14:58:07

US3412259

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

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	20 Jan 2021 14:58:07

US3412259

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:58:17

US3412259

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

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:58:17

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mRNA-1273'	System	20 Jan 2021 14:58:36
DataPoint set to visible.	System	20 Jan 2021 14:56:04

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '9:09'	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '18 Jan 2021 9:09'	System	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Left Arm (LEFT ARM)'	Mason Urban (b) (4)	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'ONCE'	System	20 Jan 2021 14:58:36

US3412259

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

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 14:58:36

US3412259

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:56:29

US3412259

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:56:29

US3412259

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '8:32'	Mason Urban (b) (4)	20 Jan 2021 14:56:29

US3412259

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '18 Jan 2021 8:32'	System	20 Jan 2021 14:56:29

US3412259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:56:40

US3412259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '18 Jan 2021'	Mason Urban (b) (4)	20 Jan 2021 14:56:40

US3412259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:32

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '8:34'	Mason Urban (b) (4)	20 Jan 2021 14:56:40

US3412259

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '18 Jan 2021 8:34'	System	20 Jan 2021 14:56:40

US3412259

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Mason Urban (b) (4)	20 Jan 2021 14:56:45

US3412259

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

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	20 Jan 2021 14:56:45

US3412259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 15:40:53

US3412259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered '25 Jan 2021'	Mason Urban (b) (4)	25 Jan 2021 15:40:53

US3412259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Jan 2021 15:40:53

US3412259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered empty.	Mason Urban (b) (4)	25 Jan 2021 15:40:53

US3412259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 15:44:30

US3412259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	25 Jan 2021 15:44:30

US3412259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	25 Jan 2021 15:44:30
DataPoint set to visible.	System	25 Jan 2021 15:44:30

US3412259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:57:35

US3412259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:57:35

US3412259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	25 Feb 2021 17:57:35

US3412259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'OLD29'	System	25 Feb 2021 17:57:35

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User accepted default value 'Pre-Dose (PREDOSE)'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10
	(b) (4)	

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '07:22'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25 Feb 2021 07:22'	System	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '97.7' F	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '63'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'bpm'	System	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '16'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'breaths/min'	System	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '138'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '92'	Andrea Newlands (b) (4)	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Feb 2021 17:58:10

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User accepted default value 'Post-Dose (POSTDOSE)'	Andrea Newlands (b) (4) (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '09:36'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25 Feb 2021 09:36'	System	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '97.7' F	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Oral (Oral)'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '65'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'bpm'	System	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '16'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'breaths/min'	System	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '123'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '80'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Feb 2021 17:59:12

US3412259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:18

US3412259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 17:59:18

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mRNA-1273'	System	25 Feb 2021 18:00:12
DataPoint set to visible.	System	25 Jan 2021 15:44:30

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Feb 2021'	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '08:59'	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25 Feb 2021 08:59'	System	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Left Arm (LEFT ARM)'	Andrea Newlands (b) (4)	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'ONCE'	System	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'INTRAMUSCULAR'	System	25 Feb 2021 18:00:12

US3412259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	25 Feb 2021 18:00:23

US3412259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	25 Feb 2021 18:00:23

US3412259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 17:03:32

US3412259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered '4 Mar 2021'	Mason Urban (b) (4)	04 Mar 2021 17:03:32

US3412259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	04 Mar 2021 17:03:32

US3412259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:35:32

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered empty.	Mason Urban (b) (4)	04 Mar 2021 17:03:32

US3412259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:38:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	04 Mar 2021 17:03:38

US3412259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:35:32

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'I'	System	04 Mar 2021 17:03:38

US3412259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:47

US3412259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:47

US3412259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:03:47

US3412259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:35:32

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'OLD57'	System	25 Mar 2021 13:03:47

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '08:14'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25 Mar 2021 08:14'	System	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '64'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'bpm'	System	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '14'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'breaths/min'	System	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '132'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '82'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered 'mmHg'	System	25 Mar 2021 13:04:36

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10

US3412259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:35:32

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10

US3412259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:45

US3412259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:35:32

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:04:45

US3412259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:05:13

US3412259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '25 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:05:13

US3412259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
User entered '08:25'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:05:13

US3412259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:03:10
User entered '25 Mar 2021 08:25'	System	25 Mar 2021 13:05:13

US3412259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:35:32

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:26
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Nov 2020 17:22:32

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	23 Nov 2020 17:50:13
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:03:02
User entered	System	20 Nov 2020 19:56:20
'USA-US061-2020-mRNA-1273-P301000013'		
User entered 'New'	(b) (4), (b) (6)	20 Nov 2020 19:56:20

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Mar 2021 01:33:07
User closed query 'Please change to " SYMPTOMATIC COVID-19 " without quotation marks' (Site from CRA).		11 Mar 2021 01:33:04
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)	19 Feb 2021 22:23:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	19 Feb 2021 22:23:58
Data point term sent to Coder	System	19 Feb 2021 22:23:49
Query 'Please change to " SYMPTOMATIC COVID-19 " without quotation marks' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	19 Feb 2021 22:23:43
Coding entries removed.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:23:33
User entered 'symptomatic COVID-19' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:23:33
User opened query 'Please change to " SYMPTOMATIC COVID-19 " without quotation marks' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 18:58:56
DataPoint Un-verified.		11 Feb 2021 18:58:41
DataPoint Verified.		02 Jan 2021 14:25:41
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)	30 Dec 2020 15:04:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	System	30 Dec 2020 15:03:07
DataPoint Un-verified.	Melissa Fuson (b) (4)	30 Dec 2020 15:02:28
Coding entries removed.	(b) (4)	
	Melissa Fuson (b) (4)	30 Dec 2020 15:02:28
User entered 'COVID-19' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	30 Dec 2020 15:02:28

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Adverse event](#)

Audit	User	Time (GMT)
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) (b) (4)	23 Nov 2020 21:38:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:38:22
Data point term sent to Coder	System	23 Nov 2020 20:59:34
Query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4) (b) (4)	23 Nov 2020 20:59:25
' canceled (Site from System). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 17:50:11
User closed query 'Please update term to Symptomatic COVID-19 (this is term from CCG Completion Guidelines to be used for all COVID AEs)' (Site from CRA).		23 Nov 2020 17:50:08
User opened query 'CDM-Coding: The verbatim SYMPTOMATIC COVID-19 cannot be referenced as reported. Please update the vrbatim as COVID - 19 and amend /update the term accordingly in the diagnosis field to enable coding.	Coder Import (b) (4) (b) (4)	23 Nov 2020 12:24:28
' (Site from System).		
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) (b) (4)	20 Nov 2020 16:44:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Nov 2020 16:44:02
Data point term sent to Coder	System	20 Nov 2020 16:42:57
Query 'Please update term to Symptomatic COVID-19 (this is term from CCG Completion Guidelines to be used for all COVID AEs)' answered with 'this term has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:42:53
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:42:44
User entered 'Symptomatic COVID-19' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	20 Nov 2020 16:42:44

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Please update term to Symptomatic COVID-19 (this is term from CCG Completion Guidelines to be used for all COVID AEs)' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:34:07
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) (b) (4)	17 Nov 2020 18:00:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 18:00:51
Data point term sent to Coder	System	17 Nov 2020 17:43:48
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:43:12
User entered 'COVID-19 (postive)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:43:12
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) (b) (4)	17 Nov 2020 17:28:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:28:50
Data point term sent to Coder	System	17 Nov 2020 17:27:36
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:27:20
User entered 'SYMPTOMATIC COVID-19' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:27:20
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) (b) (4)	17 Nov 2020 17:26:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:26:09
Data point term sent to Coder	System	17 Nov 2020 17:25:34
User entered 'COVID'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
User closed query 'ALL AEs related to COVID/illness visits are medically attended - please update' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:37
		19 Nov 2020 16:48:32
Query 'ALL AEs related to COVID/illness visits are medically attended - please update' answered with 'updated to yes, visit 1 dated 09-nov-2020' (Site from CRA).	Melissa Fuson (b) (4)	19 Nov 2020 14:19:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 14:18:03
User opened query 'ALL AEs related to COVID/illness visits are medically attended - please update' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:34:59
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:35:08
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 13:40:23
Query 'This is confirmed positive COVID - please update to yes' canceled (Site from CRA).		19 Nov 2020 13:40:20
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 13:16:35
	(b) (4)	
User opened query 'This is confirmed positive COVID - please update to yes' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:35:54
DataPoint Un-verified.		
	(b) (4), (b) (6)	18 Nov 2020 19:35:17
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:35:10
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:09
User entered '3 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 16:18:57
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Un-verified.	System	09 Dec 2020 15:06:38
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4) Steven Anderson (b) (4) (b) (4)	09 Dec 2020 15:06:38
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). DataPoint Verified.	System	09 Dec 2020 15:06:30
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Nov 2020 19:36:12
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:26:59
	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 14:39:34
User closed query 'Per source, symptoms ended on 17 Nov 2020. Please consider updating end date ' (Site from CRA).		03 Feb 2021 14:39:32
Query 'Per source, symptoms ended on 17 Nov 2020. Please consider updating end date ' answered with 'this has been updated to 17-nov-2020 due to signs and symptoms ending on this date.' (Site from CRA).	Steven Anderson (b) (4)	28 Jan 2021 20:46:55
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4)	28 Jan 2021 20:46:49
User opened query 'Per source, symptoms ended on 17 Nov 2020. Please consider updating end date ' (Site from CRA).	(b) (4), (b) (6)	28 Jan 2021 20:14:07
DataPoint Un-verified.		28 Jan 2021 20:13:44
		22 Dec 2020 17:38:36
User closed query 'PV Query: It is reported that symptoms resolved on 17Nov2020, however event end date is reported as 22Nov2020. Please update end date to 17Nov2020, or explain reason for end date reported as 22Nov2020.' (Site from Safety).		
Query 'PV Query: It is reported that symptoms resolved on 17Nov2020, however event end date is reported as 22Nov2020. Please update end date to 17Nov2020, or explain reason for end date reported as 22Nov2020.' answered with 'PER SOURCE FOR VISIT 2 ILLNESS VISIT END AE ON 22-NOV-2020. SA 09-DEC-2020' (Site from Safety).	Melissa Fuson (b) (4)	21 Dec 2020 14:34:57
User opened query 'PV Query: It is reported that symptoms resolved on 17Nov2020, however event end date is reported as 22Nov2020. Please update end date to 17Nov2020, or explain reason for end date reported as 22Nov2020.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 13:44:37
DataPoint Verified.		15 Dec 2020 16:18:59
User closed query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety).		11 Dec 2020 03:01:26

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (when symptoms have resolved).' answered with 'this AE is ended' (Site from Safety). DataPoint Un-verified.	Steven Anderson (b) (4)	09 Dec 2020 15:06:57
	Steven Anderson (b) (4)	09 Dec 2020 15:06:30
User entered '22 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Dec 2020 15:06:30
User opened query 'PV Query: Please provide the event end date (when symptoms have resolved).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	04 Dec 2020 00:12:30
		18 Nov 2020 19:36:14
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 17:26:59
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	17 Nov 2020 17:25:23
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:16
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:36:21
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered 'Not Related (NOT RELATED)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Dec 2020 03:35:21
User closed query 'please update to Not Applicable' (Site from CRA).		19 Dec 2020 03:35:15
User closed query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).		04 Dec 2020 04:36:23
Query 'please update to Not Applicable' answered with 'updated to Not Applicable per cdm query' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:37:38
Query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' answered with 'updated to Not Applicable per cdm query' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:37:28
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	03 Dec 2020 15:36:56
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 13:47:42
User opened query 'please update to Not Applicable' (Site from CRA).		02 Dec 2020 13:47:40
User opened query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).		01 Dec 2020 15:59:16
DataPoint Verified.		24 Nov 2020 18:44:47
User entered 'None (NONE)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 19:51:56
User entered '0' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Dec 2020 15:36:12
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	02 Dec 2020 13:50:45
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '1'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
User closed query 'Subject took Sudafed - please update to Yes' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 16:17:57
DataPoint Verified.		29 Dec 2020 16:17:55
Query 'Subject took Sudafed - please update to Yes' answered with 'medications listing updated with sudafed = YES' (Site from CRA).	Melissa Fuson (b) (4)	04 Dec 2020 17:38:12
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4)	03 Dec 2020 15:36:12
User opened query 'Subject took Sudafed - please update to Yes' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:51:07
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 13:50:46
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered '0'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Dec 2020 16:18:14
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Dec 2020 03:01:29
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'this ae has resolved' (Site from Safety).	Steven Anderson (b) (4)	09 Dec 2020 15:07:08
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	09 Dec 2020 15:06:30
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 00:13:24
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:47
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 01:33:26
User closed query 'Per DM CLR: Narrative = THIS SYMPTOMATIC COVID AE HAS ENDED AS OF 22 NOV 2020 DUE TO SUBJECT NOT EXPERIENCING ANY MORE SYMPTOMS. However, please note that this does not correspond to the recorded end date of this AE. Please review and reconcile data as appropriate. ' (Site from DM).		10 Mar 2021 12:35:25
Query 'Per DM CLR: Narrative = THIS SYMPTOMATIC COVID AE HAS ENDED AS OF 22 NOV 2020 DUE TO SUBJECT NOT EXPERIENCING ANY MORE SYMPTOMS. However, please note that this does not correspond to the recorded end date of this AE. Please review and reconcile data as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 14:30:41
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 14:30:35
User entered 'ONSET OF COVID-19 LIKE ILLNESS 03-NOV-2020 WITH MILD SORE THROAT. ON 05-NOV-2020 SHE DEVELOPED MILD NASAL CONGESTION BODY ACHES AND RUNNY NOSE. SHE WAS ADMINISTERED A RAPID COVID TEST BY HER WORK AND RECEIVED NOTICE OF A POSITIVE COVID TEST ON FRIDAY 06-NOV-2020. THIS SYMPTOMATIC COVID AE HAS ENDED AS OF 17 NOV 2020 DUE TO SUBJECT NOT EXPERIENCING ANY MORE SYMPTOMS.' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 14:30:35
User opened query 'Per DM CLR: Narrative = THIS SYMPTOMATIC COVID AE HAS ENDED AS OF 22 NOV 2020 DUE TO SUBJECT NOT EXPERIENCING ANY MORE SYMPTOMS. However, please note that this does not correspond to the recorded end date of this AE. Please review and reconcile data as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:35:15

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Dec 2020 03:35:44
User closed query 'Please update narrative to include study test date/result and symptom resolution date as well a status/events to end date' (Site from CRA).		19 Dec 2020 03:35:40
Query 'Please update narrative to include study test date/result and symptom resolution date as well a status/events to end date' answered with 'this narrative has been updated. ' (Site from CRA).	Steven Anderson (b) (4)	09 Dec 2020 15:13:21
User entered 'ONSET OF COVID-19 LIKE ILLNESS 03-NOV-2020 WITH MILD SORE THROAT. ON 05-NOV-2020 SHE DEVELOPED MILD NASAL CONGESTION BODY ACHES AND RUNNY NOSE. SHE WAS ADMINISTERED A RAPID COVID TEST BY HER WORK AND RECEIVED NOTICE OF A POSITIVE COVID TEST ON FRIDAY 06-NOV-2020. THIS SYMPTOMATIC COVID AE HAS ENDED AS OF 22 NOV 2020 due to subject not experiencing any more symptoms.' reason for change: Data Entry Error	(b) (4)	
User entered 'ONSET OF COVID-19 LIKE ILLNESS 03-NOV-2020 WITH MILD SORE THROAT. ON 05-NOV-2020 SHE DEVELOPED MILD NASAL CONGESTION BODY ACHES AND RUNNY NOSE. SHE WAS ADMINISTERED A RAPID COVID TEST BY HER WORK AND RECEIVED NOTICE OF A POSITIVE COVID TEST ON FRIDAY 06-NOV-2020. this symptomatic COVID ae has ended as of 22 NOV 2020.' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Dec 2020 15:13:03
	(b) (4)	
User entered 'ONSET OF COVID-19 LIKE ILLNESS 03-NOV-2020 WITH MILD SORE THROAT. ON 05-NOV-2020 SHE DEVELOPED MILD NASAL CONGESTION BODY ACHES AND RUNNY NOSE. SHE WAS ADMINISTERED A RAPID COVID TEST BY HER WORK AND RECEIVED NOTICE OF A POSITIVE COVID TEST ON FRIDAY 06-NOV-2020. this symptomatic COVID ae has ended as of 22 NOV 2020.' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Dec 2020 15:12:05
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	02 Dec 2020 13:48:08
User opened query 'Please update narrative to include study test date/result and symptom resolution date as well a status/events to end date' (Site from CRA).		02 Dec 2020 13:46:38
DataPoint Verified.		24 Nov 2020 18:44:47
User closed query 'please complete narrative' (Site from CRA).		24 Nov 2020 18:44:44

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Narrative](#)

Audit	User	Time (GMT)
Query 'please complete narrative' answered with 'UPDATED(MEF-19-NOV-2020) WITH NARRATIVE OF ADVERSE EVENT NOTED ON SOURCE FOR UNSCHEDULED VISIT 1 / ILLNESS VISIT ' (Site from CRA).	Melissa Fuson (b) (4)	19 Nov 2020 14:26:20
User entered 'ONSET OF COVID-19 LIKE ILLNESS 03-NOV-2020 WITH MILD SORE THROAT. ON 05-NOV-2020 SHE DEVELOPED MILD NASAL CONGESTION BODY ACHES AND RUNNY NOSE. SHE WAS ADMINISTERED A RAPID COVID TEST BY HER WORK AND RECEIVED NOTICE OF A POSITIVE COVID TEST ON FRIDAY 06-NOV-2020.' reason for change: Data Entry Error	Melissa Fuson (b) (4)	19 Nov 2020 14:25:15
User opened query 'please complete narrative' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 19:39:34
User entered empty.	Melissa Fuson (b) (4)	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 22:35:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Nov 2020 14:18:03
User entered '0'	System	17 Nov 2020 17:25:23

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 21:07:44
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 21:07:44
	(b) (4)	
Data point term sent to Coder	System	08 Mar 2021 21:07:08
User entered 'onychomycosis'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 21:06:07

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 21:06:07

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 17:26:55
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	07 Apr 2021 18:45:17
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:53:26
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
User entered 'I'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered 'Unknown (UNKNOWN)'	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:38:24
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Mar 2021 21:06:07
	(b) (4)	

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 21:06:07

US3412259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 22:35:32

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Mar 2021 21:06:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:26:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:42:01
User closed query 'please check Con Med log and update accordingly - Excedrin (Aspirin/Caffeine/Acetaminophen) 250/65/250 mg prn 1988 - cont for migraines, pneumovax 0.5 ml once IM for pneumonia prophylaxis and Terbinafine HCL 250 mg QD for onychomycosis starting 2 Mar 2021 - cont' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Apr 2021 20:10:56
Query 'please check Con Med log and update accordingly - Excedrin (Aspirin/Caffeine/Acetaminophen) 250/65/250 mg prn 1988 - cont for migraines, pneumovax 0.5 ml once IM for pneumonia prophylaxis and Terbinafine HCL 250 mg QD for onychomycosis starting 2 Mar 2021 - cont' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	07 Apr 2021 18:50:50
User opened query 'please check Con Med log and update accordingly - Excedrin (Aspirin/Caffeine/Acetaminophen) 250/65/250 mg prn 1988 - cont for migraines, pneumovax 0.5 ml once IM for pneumonia prophylaxis and Terbinafine HCL 250 mg QD for onychomycosis starting 2 Mar 2021 - cont' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 18:29:18
User closed query 'Per ETRTR: Medication was dosed for COVID-19 symptoms. Please update COVID-19 page to indicate Concomitant Medication was dosed, thanks.' (Site from CRA).		29 Dec 2020 16:39:06
DataPoint Verified.		29 Dec 2020 16:39:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 18:11:42
Query 'Per ETRTR: Medication was dosed for COVID-19 symptoms. Please update COVID-19 page to indicate Concomitant Medication was dosed, thanks.' answered with 'NO CON MEDS WERE TAKEN, WAS CROSSED OUT ON THE SOURCE. SUBJECT TAKES IMITREX FOR MIGRAINES' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	15 Dec 2020 18:11:28

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Dec 2020 18:11:19
User closed query 'influenza vaccine on 08 Oct 2020 per source - please confirm and add to Con Meds' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:51:19
User closed query 'per source, subject took Sudafed 08-09 Nov2020 - please confirm and add to con meds' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:50:04
User opened query 'Per ETRTR: Medication was dosed for COVID-19 symptoms. Please update COVID-19 page to indicate Concomitant Medication was dosed, thanks.' (Site from CRA).	(b) (4), (b) (6)	28 Nov 2020 00:36:09
Query 'influenza vaccine on 08 Oct 2020 per source - please confirm and add to Con Meds' answered with 'confirmed and added to con meds' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 17:40:01
Query 'per source, subject took Sudafed 08-09 Nov2020 - please confirm and add to con meds' answered with 'confirmed and added to con meds' (Site from CRA).	Melissa Fuson (b) (4)	17 Nov 2020 17:39:27
User opened query 'influenza vaccine on 08 Oct 2020 per source - please confirm and add to Con Meds' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 16:13:46
User opened query 'per source, subject took Sudafed 08-09 Nov2020 - please confirm and add to con meds' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 16:11:59
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:32:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN, PRODUCTSYNONYM: IMITREX [SUMATRIPTAN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:35:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 15:35:34
Data point term sent to Coder	System	24 Aug 2020 15:34:38
User entered 'Imitrex'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Migraine'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '100'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'un UNK 2010'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 15:33:39

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 07:03:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Aug 2020 07:03:35
Data point term sent to Coder	System	24 Aug 2020 15:35:41
User entered 'CELECOXID-CELEBREX'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'OA-SHOULDER PAIN'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '200'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '12 Jan 2020'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '0'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 15:34:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:53:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 16:53:48
Data point term sent to Coder	System	17 Nov 2020 16:52:54
User entered 'INFLUENZA VACCINE'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'GENERAL HEALTH'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	07 Apr 2021 18:46:40
	(b) (4)	
User entered '0.5' reason for change: Data Entry Error	Andrea Newlands (b) (4)	07 Apr 2021 18:46:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:55:10
	(b) (4)	
User entered '1'	Melissa Fuson (b) (4)	17 Nov 2020 16:52:41
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'mL (mL)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'once (ONCE)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '08 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '08 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User entered empty.	System	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User entered empty.	System	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:43
User entered empty.	System	17 Nov 2020 16:52:41

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED 12-HOUR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:33:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Nov 2020 08:33:15
Data point term sent to Coder	System	19 Nov 2020 13:13:06
Coding entries removed.	Melissa Fuson (b) (4)	19 Nov 2020 13:12:39
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 19:55:10
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE HYDROCHLORIDE, PRODUCTSYNONYM: SUDAFED 12-HOUR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:51:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 07:51:00
Data point term sent to Coder	System	17 Nov 2020 16:58:02
User entered 'SUDAFED - 12 HOUR'	Melissa Fuson (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User closed query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM). Query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' answered with 'it appears this has been updated and that con meds has been ticked on AE#1' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 15:06:04
User opened query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Any ConMed Administered' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM). Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' canceled (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:54:32
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:16:21
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).		05 Jan 2021 13:16:17
DataPoint Verified.		05 Jan 2021 13:16:12
		02 Dec 2020 13:49:30

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
User closed query 'please consider updating indication to symptomatic COVID-19' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 13:49:28
Query 'please consider updating indication to symptomatic COVID-19' answered with 'UPDATED PER AUDITOR - (MEF-19-N0V-2020)' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 13:13:08
User entered 'SYMPTOMATIC COVID-19 - RUNNY NOSE AND CONGESTION' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	19 Nov 2020 13:12:39
DataPoint Un-verified.	(b) (4), (b) (6)	18 Nov 2020 19:55:15
DataPoint Verified.		18 Nov 2020 19:55:10
User opened query 'please consider updating indication to symptomatic COVID-19' (Site from CRA).		18 Nov 2020 19:54:15
User entered 'RUNNY NOSE AND CONGESTION'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:54:24
User entered 'l'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:54:25
User entered 'tablet (TABLET)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'once daily (QD)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered empty.	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '08 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '0'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 16:59:16
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Nov 2020 19:55:10
User entered '9 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 16:59:16
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User closed query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:51:09
Query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' answered with 'this has been updated to reflect no. this was not indicative of a solicited event' (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:55:19
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:54:42
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:54:42
User opened query 'Per DM CLR: Please note, 'Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Please review and update eCRF. Otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 13:16:29
DataPoint Verified.		18 Nov 2020 19:55:10

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User entered '1'	System	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User entered '1'	System	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:47
User entered '804 (804)'	System	17 Nov 2020 16:57:38

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:49:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 18:49:50
Data point term sent to Coder	System	07 Apr 2021 18:48:29
Coding entries removed.	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
Coding entries removed.	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
User entered 'pneumovax' reason for change: Data Entry Error	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 16:38:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 16:38:57
Data point term sent to Coder	System	30 Nov 2020 16:38:24
User entered 'FLU VACCINE'	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'pneumonia prophylaxis' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
User entered 'GENERAL HEALTH'	(b) (4)	
	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered '0.5'	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'mL (mL)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered empty.	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered empty.	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered empty.	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered '05 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
User entered '19 Oct 2020'	(b) (4)	
	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered '0'	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered '05 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	07 Apr 2021 18:47:40
User entered '19 Oct 2020'	(b) (4)	
	Melissa Fuson (b) (4)	30 Nov 2020 16:37:36
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User entered empty.	System	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User entered empty.	System	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:15:54
User entered empty.	System	30 Nov 2020 16:37:36

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: METHYLPREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Dec 2020 23:49:50
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 Dec 2020 23:49:50
Data point term sent to Coder	System	21 Dec 2020 19:32:55
User entered 'METHYL PREGNAZOLONE'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Jan 2021 13:50:14
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'this has been changed to indicate no as this is not a prophylactic medication and is being taken for an actual condition.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	28 Jan 2021 20:56:21
DataPoint Un-verified.	Steven Anderson (b) (4)	28 Jan 2021 20:55:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	Steven Anderson (b) (4)	28 Jan 2021 20:55:52
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 07:58:23
		29 Dec 2020 16:32:15
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:17
User entered 'RIGHT SHOULDER PAIN'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:19
User entered '80'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:21
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:23
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:24
User entered 'once (ONCE)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:28
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:29
User entered empty.	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:31
User entered '5 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:33
User entered '0'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:42
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:44
User entered '5 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 16:32:46
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User entered empty.	System	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User entered empty.	System	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:16:01
User entered empty.	System	21 Dec 2020 19:32:32

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, PRODUCT: TERBINAFFINE HYDROCHLORIDE, PRODUCTSYNONYM: TERBINAFFINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 15:41:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 15:41:02
Data point term sent to Coder	System	14 Apr 2021 15:40:27
Coding entries removed.	(b) (4), (b) (6)	14 Apr 2021 15:39:47
User signature succeeded.	Richard Powell (b) (4) (b) (4)	12 Apr 2021 14:24:00
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, ATC: ANTIFUNGALS FOR SYSTEMIC USE, PRODUCT: TERBINAFFINE HYDROCHLORIDE, PRODUCTSYNONYM: TERBINAFFINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:54:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:54:40
Data point term sent to Coder	System	07 Apr 2021 18:45:24
User entered 'terbinafine hcl'	Andrea Newlands (b) (4) (b) (4)	07 Apr 2021 18:45:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:42:31
User closed query 'please correct spelling Onychomycosis' (Site from CRA).	(b) (4)	(b) (4), (b) (6) 19 Apr 2021 16:22:08
Query 'please correct spelling Onychomycosis' answered with 'updated' (Site from CRA).		14 Apr 2021 15:39:52
Signature has been broken.		14 Apr 2021 15:39:47
User entered 'Onychomycosis' reason for change: Data Entry Error		14 Apr 2021 15:39:47
User opened query 'please correct spelling Onychomycosis' (Site from CRA).		13 Apr 2021 16:37:46
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User entered 'onyvhonycosis'	(b) (4) Andrea Newlands (b) (4) (b) (4)	07 Apr 2021 18:45:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered '250'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered '02 Mar 2021'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	07 Apr 2021 18:45:07
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:45:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Apr 2021 18:45:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	07 Apr 2021 18:45:07

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL, PRODUCTSYNONYM: EXCEDRIN [ACETYLSALICYLIC ACID;CAFFEINE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:21:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 06:21:40
Data point term sent to Coder	System	07 Apr 2021 18:49:43
User entered 'excedrin (aspirin/cafeine/acetaminophen)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'migrain'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered '250/65/250'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'un UNK 1988'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:24:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	07 Apr 2021 18:49:25
	(b) (4)	

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:49:25

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:49:25

US3412259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:35:32

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Apr 2021 18:49:25

US3412259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:35:32

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:42:01
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	05 Mar 2021 15:05:58
	(b) (4)	

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:35:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
User entered '20/Nov/2020 19:56'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 22:35:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered '1'		20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'No (N)'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:35:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:29:41
User entered '10/Dec/2020 14:05'	System	10 Dec 2020 19:05:57

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 22:35:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	09 Apr 2021 12:29:41
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 17:38:14
User entered '1'		10 Dec 2020 19:05:57

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:35:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:29:41
User entered '22/Dec/2020 12:38'	System	22 Dec 2020 17:38:25

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 22:35:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:29:41
Reviewed for Safety.		23 Feb 2021 17:32:57
User entered '1'		22 Dec 2020 17:38:25

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4)	24 Nov 2020 18:44:57
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:35:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:29:41
User entered '23/Feb/2021 12:33'	System	23 Feb 2021 17:33:17

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 22:35:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:29:41
Reviewed for Safety.		10 Mar 2021 14:37:51
User entered '1'		23 Feb 2021 17:33:17

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'USA-US061-2020-MRNA-1273-P301000013'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'No (N)'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gregory'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Gottschlich'		20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '4260 Glendale Milford Road'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered 'Cincinnati'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 18:44:57
Reviewed for Safety.		20 Nov 2020 19:56:31
User entered '45242'	System	20 Nov 2020 19:56:20

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 19:05:43
DataPoint Verified.		24 Nov 2020 18:44:57
User entered 'US'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 11 Aug 2021 22:35:32

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	10 Mar 2021 14:38:12
User entered '4'	System	23 Feb 2021 17:33:17
User entered '3'	System	22 Dec 2020 17:38:25
User entered '2'	System	10 Dec 2020 19:05:57
User entered '1'	System	20 Nov 2020 19:56:41

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:35:32

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Apr 2021 12:29:41
User entered '10/Mar/2021 08:38'	System	10 Mar 2021 14:38:12

US3412259

Folder: SAE USA-US061-2020-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 22:35:32

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:56:48
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 12:29:41
User entered 'I'		10 Mar 2021 14:38:12