

US3202375 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:40:59

All time stamps listed in this document are displayed in GMT

US3202375

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 16:10:14

Generated On: 09 Jun 2021 15:40:59

[Participant ID](#)

US3202375

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

US3202375

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	56
Age Units	YEARS
Age (Derived)	56
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:29:42

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Condition	C-SECTION #1
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1985
Start Year (derived)	1985
Stop Month and Year (derived)	JAN 1985
Stop Year (derived)	1985

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Condition	C-SECTION #2
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1994
Start Year (derived)	1994
Stop Month and Year (derived)	JAN 1994
Stop Year (derived)	1994

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	01 SEP 2020
Time of assessment (<i>00:00-23:59</i>)	10:06 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:06
Height (<i>xxx.x</i>)	164.0 cm
Weight (<i>xxx.x</i>)	69.9 kg
BMI (<i>xxx.x</i>)	25.98899 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Date of assessment (dd MMM yyyy) 01 SEP 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2015

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:29:42

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

What was the date of randomization? (dd MMM yyyy) 01 SEP 2020

What was the participant's randomization number? 110551

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:29:42

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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)	01 SEP 2020
Time of assessment (00:00-23:59)	10:06 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 10:06
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	98 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	01 SEP 2020
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 11:47
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	92 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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) 1 SEP 2020

What was the treatment time? (00:00-23:59) 10:54 (24 HR)

Treatment Date and Time (derived) 1 SEP 2020 10:54

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 SEP 2020
Collection time (00:00-23:59)	10:30 (24 HR)
Collection date and time (derived)	1 SEP 2020 10:30

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Collection date (dd MMM yyyy)			1 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:27	1 SEP 2020 10:27
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 11:24

PC Open Date & Time

01 SEP 2020 11:14

PC Close Date & Time

01 SEP 2020 13:44

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	01 SEP 2020 19:45
PC Open Date & Time	01 SEP 2020 14:39
PC Close Date & Time	02 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

02 SEP 2020 21:55

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

04 SEP 2020 02:52

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 00:33

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

06 SEP 2020 19:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 21:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

01 SEP 2020 11:22

PC Open Date & Time

01 SEP 2020 11:14

PC Close Date & Time

01 SEP 2020 13:44

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

01 SEP 2020 19:44

PC Open Date & Time

01 SEP 2020 14:39

PC Close Date & Time

02 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

02 SEP 2020 21:56

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

04 SEP 2020 02:53

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 00:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

06 SEP 2020 19:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

07 SEP 2020 21:39

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 11:23
PC Open Date & Time	01 SEP 2020 11:14
PC Close Date & Time	01 SEP 2020 13:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:45
PC Open Date & Time	01 SEP 2020 14:39
PC Close Date & Time	02 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 21:56
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 02:53
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 00:36
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 21:40
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3202375

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments LVM

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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)	5 OCT 2020
Time of assessment (00:00-23:59)	08:48 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 08:48
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	5 OCT 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	5 OCT 2020 10:20
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG

US3202375

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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.

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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) 5 OCT 2020

What was the treatment time? (00:00-23:59) 09:31 (24 HR)

Treatment Date and Time (derived) 5 OCT 2020 09:31

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

US3202375

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 OCT 2020

Collection time (00:00-23:59)

09:08 (24 HR)

Collection date and time (derived)

5 OCT 2020 09:08

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Collection date (dd MMM yyyy)			5 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:05	5 OCT 2020 09:05
Nasopharyngeal Swab 2	No		

US3202375

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

05 OCT 2020 10:18

PC Open Date & Time

05 OCT 2020 09:51

PC Close Date & Time

05 OCT 2020 12:21

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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 101.1 °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	05 OCT 2020 14:01
PC Open Date & Time	05 OCT 2020 13:16
PC Close Date & Time	06 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

07 OCT 2020 11:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 10:58

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

10 OCT 2020 13:04

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 OCT 2020 07:33

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

05 OCT 2020 10:18

PC Open Date & Time

05 OCT 2020 09:51

PC Close Date & Time

05 OCT 2020 12:21

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

05 OCT 2020 14:01

PC Open Date & Time

05 OCT 2020 13:16

PC Close Date & Time

06 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

07 OCT 2020 11:50

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

08 OCT 2020 10:58

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 OCT 2020 13:04

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

12 OCT 2020 07:34

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 10:19
PC Open Date & Time	05 OCT 2020 09:51
PC Close Date & Time	05 OCT 2020 12:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

No ☒

Yes ☐

PC Time stamp	05 OCT 2020 14:02
PC Open Date & Time	05 OCT 2020 13:16
PC Close Date & Time	06 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 11:51
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

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 ☒

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 10:58
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

Yes ☐

PC Time stamp

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 13:04
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 07:34
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 13 OCT 2020 08:33

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 8

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

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 13 OCT 2020 08:34

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 13 OCT 2020 08:34

PC Open Date & Time 12 OCT 2020 12:00

PC Close Date & Time 13 OCT 2020 11:59

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	13 OCT 2020 08:34
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3202375

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 NOV 2020
Time of assessment (00:00-23:59)	14:09 (24 HR)
Vital Signs Date and Time (derived)	2 NOV 2020 14:09
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202375

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

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.

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 12:54:19

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 NOV 2020

Collection time (00:00-23:59)

14:21 (24 HR)

Collection date and time (derived)

2 NOV 2020 14:21

US3202375

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:29:42

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 08:18:19
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	False
Cough	True
Shortness of breath	True
Difficulty breathing	True
Fatigue	True
Muscle aches	True
Body aches	True
Headache	False
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	10 NOV 2020 16:00:56
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 08:57:55

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 09:51:11
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

17 DEC 2020 08:25:25

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 16:53:24

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

28 JAN 2021 16:47:29

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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 <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"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 17:33:53
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 MAR 2021 18:48:49
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

12 MAR 2021 10:16:10

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 14:22:04

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3202375

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:40:59

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		07 MAR 2021 18:49:06

US3202375

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:54:19

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:54:19

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

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

LEFT A VOICE MESSAGE

If Contact Not Made, please provide Comments

US3202375

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202375

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

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) _____

US3202375

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

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.

US3202375

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

31 MAR 2021

Collection time (00:00-23:59)

11:11 (24 HR)

Collection date and time (derived)

31 MAR 2021 11:11

US3202375

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Date of Contact	11 NOV 2020
Time of Contact	11:25
Date and Time of Contact (derived)	11 NOV 2020 11:25
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	101.6 F	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	ND - Not Done	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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 type="radio"/>
	Mild	<input checked="" 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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	99 %	
O2 Saturation Units	%	
Temperature	37.0 C	
Chills	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input checked="" type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	99 %	
O2 Saturation Units	%	
Temperature	99.4 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	98 %	
O2 Saturation Units	%	
Temperature	99.2 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	99 %	
O2 Saturation Units	%	
Temperature	99.0 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

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Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	99.0 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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

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Form: Symptom Log (7)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	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 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	98 %	
O2 Saturation Units	%	
Temperature	99.4 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 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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	98.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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	98 %	
O2 Saturation Units	%	
Temperature	98.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input 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)

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US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

	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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Date of Visit	11 NOV 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	11 NOV 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Date of Contact	30 SEP 2020
Time of Contact	10:54
Date and Time of Contact (derived)	30 SEP 2020 10:54
Type of Contact	Clinic Visit - Scheduled <input checked="" type="radio"/>
	Clinical Visit - Unscheduled <input type="radio"/>
	Safety Call <input type="radio"/>
	Convalescent Tele-visit <input type="radio"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

Date	26 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	27 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Form: Symptom Log (2)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

Date	28 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

Date	29 SEP 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 SEP 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	36.6 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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

	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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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"/>

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

	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	1 OCT 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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 ☐

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Date of Visit	30 SEP 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	30 SEP 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

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

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 16:10:16

Generated On: 09 Jun 2021 15:40:59

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	13 NOV 2020
Day 5	Yes	15 NOV 2020
Day 7	Yes	17 NOV 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	SICKD1

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 11:00
Height (xxx.x)	ND - Not Done
Weight (xxx.x)	ND - Not Done
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

30 SEP 2020

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

US3202375

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

30 SEP 2020

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 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

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 NOV 2020
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	11 NOV 2020 11:30
Height (xxx.x)	64 in
Weight (xxx.x)	157.0 kg
Temperature (xxx.x)	37.0 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 NOV 2020

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

US3202375

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 09 Apr 2021 16:10:17

Generated On: 09 Jun 2021 15:40:59

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

11 NOV 2020

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID SICKD28

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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) _____

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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.

US3202375

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☒

Date of Collection

US3202375

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

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

Visit date (dd MMM yyyy)	1 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	UNBLND_DECIDE
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US3202375

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 18:03:35

Generated On: 09 Jun 2021 15:40:59

Date of updated informed consent (dd MMM yyyy) 1 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 1 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3202375

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	1 FEB 2021 10:50

US3202375

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 16:10:37

Generated On: 09 Jun 2021 15:40:59

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 FEB 2021
Collection time (00:00 - 23:59)	10:48
Collection Date and Time (derived)	1 FEB 2021 10:48

US3202375

Folder: Unscheduled (2)

Form: Unscheduled Visit Assessment

Generated On: 09 Jun 2021 15:40:59

Visit Date	
Please check all assessments that apply for this visit	
Physical Exam	
Vital Signs	
Immunogenicity Assessment	
Pregnancy Test	

US3202375

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:17:58

Generated On: 09 Jun 2021 15:40:59

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

AEID

Adverse event

UPPER RESPIRATORY
INFECTION OF UNKNOWN
CAUSE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

28 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

30 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

AEID	USA-US128-2021-MRNA-1273-P30 1000016
Adverse event	SUDDEN DEATH (UNKNOWN CAUSE)
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)	04 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	04 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	True
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input checked="" 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 type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

UPDATE23APR21--MEDICAL
EXAMINER CONTACTED ON
23APR21 AND CONFIRMED
THAT NO UPDATED CAUSE OF
DEATH LISTED YET--WILL
SEND TO SITE WHEN UPDATED
INFORMATION/FINAL CAUSE
ENTERED. SUBJECT'S DATE OF
DEATH UPDATED PER DEATH
CERTIFICATE (WAS
ORIGINALLY NOTED AS
02APR2021 DUE TO
MISCOMMUNICATION
BETWEEN GRIEVING FAMILY
AND SITE STAFF ON DATE
FIRST REPORTED. JUST
NOTICED THAT ACTUAL DATE
OF DEATH WAS
04APR2021.-UPDATE--SUBJECT'S
BODY CREMATED PRIOR TO
AUTOPSY BECAUSE FAMILY
THOUGHT THAT THE AUTOPSY
WAS COMPLETE WHEN BODY
WAS RELEASED. TOXICOLOGY
NEGATIVE AND FOUL PLAY
WAS RULED OUT PER
HUSBAND WITH PROBABLE
CAUSE OF DEATH CARDIAC
ARREST OR ABDOMINAL
AORTIC ANEURYSM BUT
NEITHER CONFIRMED. CAUSE
OF DEATH NOT YET
KNOWN--SUBJECT'S SPOUSE
REPORTED DEATH TO SITE ON
05APR2021. AWAITING

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

AUTOPSY REPORT. SUBJECT
WAS DISCOVERED BY FAMILY
MEMBER DECEASED WITH NO
KNOWN PREEXISTING ILLNESS.
SUBJECT HAD COMPLAINED OF
NAUSEA AND FEELING ILL A
BIT EARLIER SO WENT TO BED
AND WAS LATER FOUND
DECEASED. STILL AWAITING
AUTOPSY RESULTS AND
FAMILY REPORTED STILL NO
KNOWN CAUSE OF DEATH
WHEN F/UP CALL PLACED ON
09APR2021

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

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

AEID

Adverse event

UPPER RESPIRATORY
INFECTION OF UNKNOWN
CAUSE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

09 NOV 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

20 NOV 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 28 Apr 2021 07:02:30

Generated On: 09 Jun 2021 15:40:59

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	ILLNESS VISIT COMPLETED ON 11NOV2020 AND RESULTS OF COVID-19 TEST WERE NEGATIVE
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)	
PRODUCTION RELEASE (v12.003 EAB) (1725)	
268 of 2309	

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

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

Yes ☒

No ☐

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

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:23:12

Generated On: 09 Jun 2021 15:40:59

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION OF UNKNOWN
CAUSE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 19:23:12

Generated On: 09 Jun 2021 15:40:59

	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)		28 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		20 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3202375

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 16:10:15

Generated On: 09 Jun 2021 15:40:59

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3202375

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

Date of study discontinuation/completion (dd MMM yyyy) 4 APR 2021

Reason for discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Complete	<input type="checkbox"/>
Death	<input checked="" type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Other	<input type="checkbox"/>

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	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>
Other	<input type="checkbox"/>

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 04 APR 2021

Was autopsy performed?

Yes	<input type="checkbox"/>
No	<input checked="" type="checkbox"/>
Unknown	<input type="checkbox"/>

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

SAEID	USA-US128-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

SAEID	USA-US128-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	06/APR/2021 13:58
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

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

SAEID	USA-US128-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	12/APR/2021 14:57
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

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

SAEID	USA-US128-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	15/APR/2021 11:58
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

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 07:06:10

Generated On: 09 Jun 2021 15:40:59

SAEID	USA-US128-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input checked="" type="radio"/> No <input 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	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/APR/2021 12:58
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

US3202375 (Prod: WR-ClinSearch, LLC)

US3202375

Form: Participant Creation

Generated On: 09 Jun 2021 15:40:59

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:52:43
User entered 'US3202375'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:20

US3202375

Form: Participant Creation

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:09

US3202375

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:21

US3202375

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:09

US3202375

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'SCRN'	System	01 Sep 2020 15:12:09

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered (b) (6) 1964'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:22

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '56'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'YEARS'	System	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '56'	System	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User closed query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 18:50:19
Query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' answered with 'fixed' (Site from DM).	zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:01:55
User opened query 'Per CDM: Sex is recoded as 'Female'. however childbearing potential should be Indicated as 'Yes or No'. Please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 18:27:52
User entered 'Female (F)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'I'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:40:59

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:07

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '1 Sep 2020'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Sep 2020'	System	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '2020'	System	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Amendment 3 (3)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:19

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 13:50:21

US3202375

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:40:59

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'I'	System	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:40:59

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:32

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 14:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 14:03:49
Data point term sent to Coder	System	12 Sep 2020 14:03:26
User entered 'C-section #1'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'un UNK 1985'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'un UNK 1985'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Jan 1985'	System	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '1985'	System	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Jan 1985'	System	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '1985'	System	12 Sep 2020 14:02:52

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	12 Sep 2020 14:03:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Sep 2020 14:03:49
Data point term sent to Coder	System	12 Sep 2020 14:03:26
User entered 'c-section #2'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'un UNK 1994'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'un UNK 1994'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Jan 1994'	System	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '1994'	System	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Jan 1994'	System	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '1994'	System	12 Sep 2020 14:03:08

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 16:58:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Oct 2020 16:58:30
Data point term sent to Coder	System	10 Oct 2020 16:58:12
User entered 'Postmenopausal'	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	Tiffany Jewell (b) (4)	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'Jan 2015'	System	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '2015'	System	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered empty.	System	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered empty.	System	10 Oct 2020 16:57:53

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:06'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '01 Sep 2020 10:06'	System	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '164.0' cm	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02
DataPoint set to visible.	(b) (4) System	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '69.9' kg	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02
DataPoint set to visible.	(b) (4) System	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered '25.98899'	System	12 Sep 2020 14:06:02
DataPoint set to visible.	System	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'kg/m2'	System	12 Sep 2020 14:06:02
DataPoint set to visible.	System	01 Sep 2020 15:12:24

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'bpm'	System	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'breaths/min'	System	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'mmHg'	System	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User entered 'mmHg'	System	12 Sep 2020 14:06:02

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33

US3202375

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33

US3202375

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:04:51

US3202375

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:04:51

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User closed query 'Per DM CLR: 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)	05 Nov 2020 13:00:41
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate.' answered with 'Fields updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	10 Oct 2020 17:05:05
User opened query 'Per DM CLR: 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)	09 Oct 2020 14:34:09
User entered 'Post-menopausal (POST-MENOPAUSAL)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'un UNK 2015'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:40:59

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:05

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'I'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22
	(b) (4)	

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:40:59

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:17:33
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:05:22

US3202375

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 30 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 06:46:35
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 30 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' answered with 'updated' (Site from DM).	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:33:20
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Re Query: Thank you for the response, As per the CCG v 2, please add illness folder using ADD EVENT DROP Down. Please review and update the EDC as the sample dated 30 SEP 2020 is reported under Illness Visit Day 1 in PPD Central lab. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:41:51
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 04:41:51

US3202375

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'seen 30-sep for illness vs. covid neg. vs 2 rescheduled. subj completed vs 2 05-oct.lab results for both days neg for covid.' (Site from DM).	Teresa Deese (b) (4)	30 Oct 2020 18:07:33
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 30 SEP 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 23:04:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	01 Sep 2020 15:12:33

US3202375

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '1 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:12:33

US3202375

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:12:33

US3202375

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'VISIT1'	System	01 Sep 2020 15:12:33

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:19:59

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '110551'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:19:59

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 14:19:59

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Sep 2020 15:12:54
Query ' PER CDM: Please complete this section of the form' answered with 'Fields completed' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 22:05:29
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	03 Sep 2020 22:05:25
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:30:53

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	Tiffany Jewell (b) (4)	03 Sep 2020 22:05:25

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:05:25

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:05:25

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	03 Sep 2020 22:05:25

US3202375

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:47
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:53:13
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:53:11

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:06'	(b) (4) zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '01 Sep 2020 10:06'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '37.1' C	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '75'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'bpm'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '16'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'breaths/min'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '148'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'mmHg'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '98'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'mmHg'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:40:59

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '01 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '11:47'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '01 Sep 2020 11:47'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '36.3' C	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '74'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'bpm'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '18'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'breaths/min'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '137'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'mmHg'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '92'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:48
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'mmHg'	System	12 Sep 2020 14:06:48

US3202375

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:52
	(b) (4)	

US3202375

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:06:52

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

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)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '1 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:54'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '1 Sep 2020 10:54'	System	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'ONCE'	System	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 15:13:01

US3202375

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:27

US3202375

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '1 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:27

US3202375

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:30'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:27

US3202375

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '1 Sep 2020 10:30'	System	01 Sep 2020 15:42:27

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '1 Sep 2020'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:27'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '1 Sep 2020 10:27'	System	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered empty.	System	01 Sep 2020 15:42:40

US3202375

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	01 Sep 2020 15:42:03

US3202375

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'I'	System	01 Sep 2020 15:42:03

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '49d1cdb0-0022-402b-a1ae-6ccba5d6383'	System	01 Sep 2020 15:24:02
User entered 'Yes (Y)'	System	01 Sep 2020 15:24:02

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '49d1cdb0-0022-402b-a1ae-6ccba5d6383'	System	01 Sep 2020 15:24:02
User entered '98.7'	System	01 Sep 2020 15:24:02

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '49d1cdb0-0022-402b-a1ae-6ccba5d6383'	System	01 Sep 2020 15:24:02
User entered 'No (N)'	System	01 Sep 2020 15:24:02

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:24:01', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '49d1cdb0-0022-402b-a1ae-6ccbaf5d6383'	System	01 Sep 2020 15:24:02
User entered '01 Sep 2020 11:24'	System	01 Sep 2020 15:24:02

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 11:14'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:34', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '592e2f1f-c93e-455d-b7f8-bccdd0ec5291'	System	01 Sep 2020 23:45:54
User entered 'Yes (Y)'	System	01 Sep 2020 23:45:54

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:41', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '592e2f1f-c93e-455d-b7f8-bccdd0ec5291'	System	01 Sep 2020 23:45:54
User entered '98.6'	System	01 Sep 2020 23:45:54

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '592e2f1f-c93e-455d-b7f8-bccdd0ec5291'	System	01 Sep 2020 23:45:54
User entered 'No (N)'	System	01 Sep 2020 23:45:54

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '592e2f1f-c93e-455d-b7f8-bccdd0ec5291'	System	01 Sep 2020 23:45:54
User entered '01 Sep 2020 19:45'	System	01 Sep 2020 23:45:54

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 14:39'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 2'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:55:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '2608b52a-4c1c-4bf2-9219-ff1f159bf11d'	System	03 Sep 2020 01:56:01
User entered 'Yes (Y)'	System	03 Sep 2020 01:56:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:55:51', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '2608b52a-4c1c-4bf2-9219-ff1f159bf11d' User entered '98.3'	System	03 Sep 2020 01:56:01
	System	03 Sep 2020 01:56:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:55:54', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '2608b52a-4c1c-4bf2-9219-ff1f159bf11d'	System	03 Sep 2020 01:56:01
User entered 'No (N)'	System	03 Sep 2020 01:56:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:55:58', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '2608b52a-4c1c-4bf2-9219-ff1f159bf11d'	System	03 Sep 2020 01:56:01
User entered '02 Sep 2020 21:55'	System	03 Sep 2020 01:56:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 3'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '87f37249-964d-4f9e-ac05-df8743c06ebe'	System	04 Sep 2020 06:52:48
User entered 'Yes (Y)'	System	04 Sep 2020 06:52:48

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:36', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '87f37249-964d-4f9e-ac05-df8743c06ebe'	System	04 Sep 2020 06:52:48
User entered '98.9'	System	04 Sep 2020 06:52:48

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:39', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '87f37249-964d-4f9e-ac05-df8743c06ebe'	System	04 Sep 2020 06:52:48
User entered 'No (N)'	System	04 Sep 2020 06:52:48

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:41', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '87f37249-964d-4f9e-ac05-df8743c06ebe'	System	04 Sep 2020 06:52:48
User entered '04 Sep 2020 02:52'	System	04 Sep 2020 06:52:48

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 4'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:33:09', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '60247280-5e08-457c-b86f-36e062aa39f7'	System	05 Sep 2020 04:33:29
User entered 'Yes (Y)'	System	05 Sep 2020 04:33:29

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:33:17', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '60247280-5e08-457c-b86f-36e062aa39f7'	System	05 Sep 2020 04:33:29
User entered '98.4'	System	05 Sep 2020 04:33:29

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:33:21', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '60247280-5e08-457c-b86f-36e062aa39f7'	System	05 Sep 2020 04:33:29
User entered 'No (N)'	System	05 Sep 2020 04:33:29

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:33:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '60247280-5e08-457c-b86f-36e062aa39f7'	System	05 Sep 2020 04:33:29
User entered '05 Sep 2020 00:33'	System	05 Sep 2020 04:33:29

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 5'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 6'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:02', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128b3589-aade-4cba-8676-fa9cda4f52bc'	System	06 Sep 2020 23:57:24
User entered 'Yes (Y)'	System	06 Sep 2020 23:57:24

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:11', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128b3589-aade-4cba-8676-fa9cda4f52bc'	System	06 Sep 2020 23:57:24
User entered '98.4'	System	06 Sep 2020 23:57:24

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:14', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128b3589-aade-4cba-8676-fa9cda4f52bc'	System	06 Sep 2020 23:57:24
User entered 'No (N)'	System	06 Sep 2020 23:57:24

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128b3589-aade-4cba-8676-fa9cda4f52bc'	System	06 Sep 2020 23:57:24
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:24

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 7'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a62fd3-31dd-47a7-bda9-977364885180'	System	08 Sep 2020 01:39:49
User entered 'Yes (Y)'	System	08 Sep 2020 01:39:49

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a62fd3-31dd-47a7-bda9-977364885180'	System	08 Sep 2020 01:39:49
User entered '98.6'	System	08 Sep 2020 01:39:49

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:38', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a62fd3-31dd-47a7-bda9-977364885180'	System	08 Sep 2020 01:39:49
User entered 'No (N)'	System	08 Sep 2020 01:39:49

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a62fd3-31dd-47a7-bda9-977364885180'	System	08 Sep 2020 01:39:49
User entered '07 Sep 2020 21:39'	System	08 Sep 2020 01:39:49

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:22:17', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '235e3e6f-9004-4a4f-9c6b-ed287b753848'	System	01 Sep 2020 15:22:56
User entered 'None (1)'	System	01 Sep 2020 15:22:56

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:22:36', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '235e3e6f-9004-4a4f-9c6b-ed287b753848'	System	01 Sep 2020 15:22:56
User entered 'No (N)'	System	01 Sep 2020 15:22:56

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:22:41', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '235e3e6f-9004-4a4f-9c6b-ed287b753848'	System	01 Sep 2020 15:22:56
User entered 'No (N)'	System	01 Sep 2020 15:22:56

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:22:47', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '235e3e6f-9004-4a4f-9c6b-ed287b753848'	System	01 Sep 2020 15:22:56
User entered 'None (1)'	System	01 Sep 2020 15:22:56

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:22:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '235e3e6f-9004-4a4f-9c6b-ed287b753848'	System	01 Sep 2020 15:22:56
User entered '01 Sep 2020 11:22'	System	01 Sep 2020 15:22:56

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 11:14'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '270e7afc-d816-4047-a8fb-57b17eb05888'	System	01 Sep 2020 23:44:50
User entered 'None (1)'	System	01 Sep 2020 23:44:50

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:34', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '270e7afc-d816-4047-a8fb-57b17eb05888'	System	01 Sep 2020 23:44:50
User entered 'No (N)'	System	01 Sep 2020 23:44:50

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:38', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '270e7afc-d816-4047-a8fb-57b17eb05888'	System	01 Sep 2020 23:44:50
User entered 'No (N)'	System	01 Sep 2020 23:44:50

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '270e7afc-d816-4047-a8fb-57b17eb05888'	System	01 Sep 2020 23:44:50
User entered 'None (1)'	System	01 Sep 2020 23:44:50

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:46', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '270e7afc-d816-4047-a8fb-57b17eb05888'	System	01 Sep 2020 23:44:50
User entered '01 Sep 2020 19:44'	System	01 Sep 2020 23:44:50

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 14:39'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 2'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:10', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12b2d1fa-fdc8-4fc9-af9b-9d88e6835628'	System	03 Sep 2020 01:56:28
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 01:56:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12b2d1fa-fdc8-4fc9-af9b-9d88e6835628'	System	03 Sep 2020 01:56:28
User entered 'No (N)'	System	03 Sep 2020 01:56:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:17', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12b2d1fa-fdc8-4fc9-af9b-9d88e6835628'	System	03 Sep 2020 01:56:28
User entered 'No (N)'	System	03 Sep 2020 01:56:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:21', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12b2d1fa-fdc8-4fc9-af9b-9d88e6835628'	System	03 Sep 2020 01:56:28
User entered 'None (1)'	System	03 Sep 2020 01:56:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12b2d1fa-fdc8-4fc9-af9b-9d88e6835628'	System	03 Sep 2020 01:56:28
User entered '02 Sep 2020 21:56'	System	03 Sep 2020 01:56:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 3'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '53808b1b-6d08-44dc-b3d3-da9047699c80'	System	04 Sep 2020 06:53:14
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 06:53:14

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:52:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '53808b1b-6d08-44dc-b3d3-da9047699c80'	System	04 Sep 2020 06:53:14
User entered 'No (N)'	System	04 Sep 2020 06:53:14

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '53808b1b-6d08-44dc-b3d3-da9047699c80'	System	04 Sep 2020 06:53:14
User entered 'No (N)'	System	04 Sep 2020 06:53:14

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '53808b1b-6d08-44dc-b3d3-da9047699c80'	System	04 Sep 2020 06:53:14
User entered 'None (1)'	System	04 Sep 2020 06:53:14

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:11', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '53808b1b-6d08-44dc-b3d3-da9047699c80'	System	04 Sep 2020 06:53:14
User entered '04 Sep 2020 02:53'	System	04 Sep 2020 06:53:14

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 4'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:06', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c90165d4-9120-45b5-88b4-696b189e00fd'	System	05 Sep 2020 04:36:28
User entered 'None (1)'	System	05 Sep 2020 04:36:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:09', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c90165d4-9120-45b5-88b4-696b189e00fd'	System	05 Sep 2020 04:36:28
User entered 'No (N)'	System	05 Sep 2020 04:36:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:12', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c90165d4-9120-45b5-88b4-696b189e00fd'	System	05 Sep 2020 04:36:28
User entered 'No (N)'	System	05 Sep 2020 04:36:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c90165d4-9120-45b5-88b4-696b189e00fd'	System	05 Sep 2020 04:36:28
User entered 'None (1)'	System	05 Sep 2020 04:36:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:20', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c90165d4-9120-45b5-88b4-696b189e00fd' User entered '05 Sep 2020 00:36'	System	05 Sep 2020 04:36:28
	System	05 Sep 2020 04:36:28

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 5'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 6'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:22', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5d503d76-5cf7-4ce8-86fe-a128583daa9c'	System	06 Sep 2020 23:57:37
User entered 'None (1)'	System	06 Sep 2020 23:57:37

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5d503d76-5cf7-4ce8-86fe-a128583daa9c'	System	06 Sep 2020 23:57:37
User entered 'No (N)'	System	06 Sep 2020 23:57:37

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:28', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5d503d76-5cf7-4ce8-86fe-a128583daa9c'	System	06 Sep 2020 23:57:37
User entered 'No (N)'	System	06 Sep 2020 23:57:37

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5d503d76-5cf7-4ce8-86fe-a128583daa9c'	System	06 Sep 2020 23:57:37
User entered 'None (1)'	System	06 Sep 2020 23:57:37

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:33', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5d503d76-5cf7-4ce8-86fe-a128583daa9c'	System	06 Sep 2020 23:57:37
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:37

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 7'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:46', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c6b54211-708b-4acd-b6cc-f96d441565ff'	System	08 Sep 2020 01:40:02
User entered 'None (1)'	System	08 Sep 2020 01:40:02

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c6b54211-708b-4acd-b6cc-f96d441565ff'	System	08 Sep 2020 01:40:02
User entered 'No (N)'	System	08 Sep 2020 01:40:02

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:51', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c6b54211-708b-4acd-b6cc-f96d441565ff'	System	08 Sep 2020 01:40:02
User entered 'No (N)'	System	08 Sep 2020 01:40:02

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c6b54211-708b-4acd-b6cc-f96d441565ff'	System	08 Sep 2020 01:40:02
User entered 'None (1)'	System	08 Sep 2020 01:40:02

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:39:56', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c6b54211-708b-4acd-b6cc-f96d441565ff'	System	08 Sep 2020 01:40:02
User entered '07 Sep 2020 21:39'	System	08 Sep 2020 01:40:02

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:02', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a'	System	01 Sep 2020 15:23:39
User entered 'None (0)'	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:05', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a' User entered 'None (0)'	System	01 Sep 2020 15:23:39
	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a' User entered 'None (0)'	System	01 Sep 2020 15:23:39
	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:11', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a' User entered 'None (0)'	System	01 Sep 2020 15:23:39
	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:22', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a'	System	01 Sep 2020 15:23:39
User entered 'None (0)'	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a'	System	01 Sep 2020 15:23:39
User entered 'None (0)'	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:31', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a'	System	01 Sep 2020 15:23:39
User entered 'No (N)'	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T11:23:34', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '11e80009-abf4-432e-866e-84d3d957d87a'	System	01 Sep 2020 15:23:39
User entered '01 Sep 2020 11:23'	System	01 Sep 2020 15:23:39

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 11:14'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 13:44'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:51', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be' User entered 'None (0)'	System	01 Sep 2020 23:45:19
	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:55', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be'	System	01 Sep 2020 23:45:19
User entered 'None (0)'	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:44:58', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be' User entered 'None (0)'	System	01 Sep 2020 23:45:19
	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:01', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be' User entered 'None (0)'	System	01 Sep 2020 23:45:19
	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be' User entered 'None (0)'	System	01 Sep 2020 23:45:19
	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:07', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be'	System	01 Sep 2020 23:45:19
User entered 'None (0)'	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:15', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be'	System	01 Sep 2020 23:45:19
User entered 'No (N)'	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-01T19:45:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '6ce2d620-6a08-4aee-b3b5-586800c235be'	System	01 Sep 2020 23:45:19
User entered '01 Sep 2020 19:45'	System	01 Sep 2020 23:45:19

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '01 Sep 2020 14:39'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 2'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:34', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:43', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'None (0)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:51', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered 'No (N)'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-02T21:56:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '4590e48f-c8f2-482b-a3da-a7e80ab2a0ad'	System	03 Sep 2020 01:56:56
User entered '02 Sep 2020 21:56'	System	03 Sep 2020 01:56:56

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 3'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:19', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:22', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:26', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:33', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'None (0)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered 'No (N)'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-04T02:53:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'ebf4dbba-c22b-4529-ab55-a5e2e451005f'	System	04 Sep 2020 06:53:44
User entered '04 Sep 2020 02:53'	System	04 Sep 2020 06:53:44

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 4'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:27', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:30', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:32', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:34', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'None (0)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered 'No (N)'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-05T00:36:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8dd3a60c-2f79-4e14-8e32-bf08ea8a5463'	System	05 Sep 2020 04:36:49
User entered '05 Sep 2020 00:36'	System	05 Sep 2020 04:36:49

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 5'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 6'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:39', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:44', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:47', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'None (0)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:56', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered 'No (N)'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-06T19:57:59', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '123bdbc5-3d9d-440e-890f-b78102291cef'	System	06 Sep 2020 23:58:03
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:58:03

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 7'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:01', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:03', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:05', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:06', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:09', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'None (0)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered 'No (N)'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-09-07T21:40:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '93647b42-0c88-4ef1-a5fa-6d7f7a8c07e3'	System	08 Sep 2020 01:40:20
User entered '07 Sep 2020 21:40'	System	08 Sep 2020 01:40:20

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 15:13:01

US3202375

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:07:07

US3202375

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '08 Sep 2020'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:07:07
	(b) (4)	

US3202375

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:07:07

US3202375

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:07:07
	(b) (4)	

US3202375

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:07:31
	(b) (4)	

US3202375

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered 'I'	System	12 Sep 2020 14:07:31

US3202375

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:07
	(b) (4)	

US3202375

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '15 Sep 2020'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:07
	(b) (4)	

US3202375

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:07

US3202375

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:07
	(b) (4)	

US3202375

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:12

US3202375

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:53:03
User entered '1'	System	30 Sep 2020 18:02:12

US3202375

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
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).	(b) (4) System	30 Sep 2020 18:02:33
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:02:33
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	30 Sep 2020 18:02:27
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:02:27

US3202375

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '22 Sep 2020'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:27

US3202375

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:27

US3202375

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'LVM'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:02:27
	(b) (4)	

US3202375

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	05 Oct 2020 13:58:08

US3202375

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:32
User entered 'I'	System	05 Oct 2020 13:58:08

US3202375

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:21

US3202375

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:21

US3202375

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[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 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Clinic (Clinic)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:21

US3202375

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'VISIT2'	System	05 Oct 2020 13:58:21

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44
	(b) (4)	

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '08:48'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '5 Oct 2020 08:48'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '36.5' C	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '72'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'bpm'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'breaths/min'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '110'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '75'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '10:20'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '5 Oct 2020 10:20'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '36.8' C	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Oral (Oral)'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '69'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'bpm'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '18'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'breaths/min'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '108'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '73'	(b) (4) Tiffany Jewell (b) (4)	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	10 Oct 2020 16:59:44

US3202375

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:31

US3202375

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:31

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

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)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'MRNA-1273 OR PLACEBO'	System	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '09:31'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '5 Oct 2020 09:31'	System	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Left Arm (LEFT ARM)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'ONCE'	System	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:40:59

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'INTRAMUSCULAR'	System	05 Oct 2020 13:58:58

US3202375

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:36

US3202375

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:36

US3202375

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '09:08'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:36

US3202375

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '5 Oct 2020 09:08'	System	05 Oct 2020 14:36:36

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '5 Oct 2020'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '09:05'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '5 Oct 2020 09:05'	System	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered empty.	System	05 Oct 2020 14:36:24

US3202375

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Tiffany Jewell (b) (4)	05 Oct 2020 13:59:10

US3202375

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '1'	System	05 Oct 2020 13:59:10

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:20', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a9086c-5c5c-4017-b377-537f62fcc602'	System	05 Oct 2020 14:18:40
User entered 'Yes (Y)'	System	05 Oct 2020 14:18:40

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:26', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a9086c-5c5c-4017-b377-537f62fcc602'	System	05 Oct 2020 14:18:40
User entered '98.2'	System	05 Oct 2020 14:18:40

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:29', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a9086c-5c5c-4017-b377-537f62fcc602'	System	05 Oct 2020 14:18:40
User entered 'No (N)'	System	05 Oct 2020 14:18:40

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:32', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '12a9086c-5c5c-4017-b377-537f62fcc602'	System	05 Oct 2020 14:18:40
User entered '05 Oct 2020 10:18'	System	05 Oct 2020 14:18:40

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 09:51'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 12:21'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:00:46', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fd09c970-ce4f-4987-a812-c33a92108c35'	System	05 Oct 2020 18:01:09
User entered 'Yes (Y)'	System	05 Oct 2020 18:01:09

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:00:54', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fd09c970-ce4f-4987-a812-c33a92108c35'	System	05 Oct 2020 18:01:09
User entered '101.1'	System	05 Oct 2020 18:01:09

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:00:56', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fd09c970-ce4f-4987-a812-c33a92108c35'	System	05 Oct 2020 18:01:09
User entered 'No (N)'	System	05 Oct 2020 18:01:09

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fd09c970-ce4f-4987-a812-c33a92108c35'	System	05 Oct 2020 18:01:09
User entered '05 Oct 2020 14:01'	System	05 Oct 2020 18:01:09

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 13:16'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 2'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:47', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '23bdc4a4-5d22-48a0-a766-de009ead3212'	System	07 Oct 2020 15:50:57
User entered 'Yes (Y)'	System	07 Oct 2020 15:50:57

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:39', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '23bdc4a4-5d22-48a0-a766-de009ead3212' User entered '98.4'	System	07 Oct 2020 15:50:57
	System	07 Oct 2020 15:50:57

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '23bdc4a4-5d22-48a0-a766-de009ead3212'	System	07 Oct 2020 15:50:57
User entered 'No (N)'	System	07 Oct 2020 15:50:57

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '23bdc4a4-5d22-48a0-a766-de009ead3212'	System	07 Oct 2020 15:50:57
User entered '07 Oct 2020 11:50'	System	07 Oct 2020 15:50:57

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 3'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:09', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'eca83612-feec-4125-9504-744ad14202f0'	System	08 Oct 2020 14:58:38
User entered 'Yes (Y)'	System	08 Oct 2020 14:58:38

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:15', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'eca83612-feec-4125-9504-744ad14202f0'	System	08 Oct 2020 14:58:38
User entered '98.9'	System	08 Oct 2020 14:58:38

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:17', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'eca83612-feec-4125-9504-744ad14202f0'	System	08 Oct 2020 14:58:38
User entered 'No (N)'	System	08 Oct 2020 14:58:38

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:33', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'eca83612-feec-4125-9504-744ad14202f0'	System	08 Oct 2020 14:58:38
User entered '08 Oct 2020 10:58'	System	08 Oct 2020 14:58:38

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 4'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 5'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 6'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5768432e-6f33-4df4-8ab4-874cee776894'	System	10 Oct 2020 17:04:22
User entered 'Yes (Y)'	System	10 Oct 2020 17:04:22

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5768432e-6f33-4df4-8ab4-874cee776894'	System	10 Oct 2020 17:04:22
User entered '98.9'	System	10 Oct 2020 17:04:22

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5768432e-6f33-4df4-8ab4-874cee776894'	System	10 Oct 2020 17:04:22
User entered 'No (N)'	System	10 Oct 2020 17:04:22

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5768432e-6f33-4df4-8ab4-874cee776894'	System	10 Oct 2020 17:04:22
User entered '10 Oct 2020 13:04'	System	10 Oct 2020 17:04:22

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 7'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:33:38', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '9ae463e3-7b97-4d69-8ef8-52abf1d62ae9'	System	12 Oct 2020 11:34:02
User entered 'Yes (Y)'	System	12 Oct 2020 11:34:02

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:33:48', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '9ae463e3-7b97-4d69-8ef8-52abf1d62ae9'	System	12 Oct 2020 11:34:02
User entered '99.0'	System	12 Oct 2020 11:34:02

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:33:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '9ae463e3-7b97-4d69-8ef8-52abf1d62ae9'	System	12 Oct 2020 11:34:02
User entered 'No (N)'	System	12 Oct 2020 11:34:02

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:33:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '9ae463e3-7b97-4d69-8ef8-52abf1d62ae9'	System	12 Oct 2020 11:34:02
User entered '12 Oct 2020 07:33'	System	12 Oct 2020 11:34:02

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a864634e-ad33-45ff-ae76-baad29e277fc'	System	05 Oct 2020 14:18:56
User entered 'None (1)'	System	05 Oct 2020 14:18:56

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:43', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a864634e-ad33-45ff-ae76-baad29e277fc'	System	05 Oct 2020 14:18:56
User entered 'No (N)'	System	05 Oct 2020 14:18:56

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:46', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a864634e-ad33-45ff-ae76-baad29e277fc'	System	05 Oct 2020 14:18:56
User entered 'No (N)'	System	05 Oct 2020 14:18:56

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a864634e-ad33-45ff-ae76-baad29e277fc'	System	05 Oct 2020 14:18:56
User entered 'None (1)'	System	05 Oct 2020 14:18:56

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a864634e-ad33-45ff-ae76-baad29e277fc'	System	05 Oct 2020 14:18:56
User entered '05 Oct 2020 10:18'	System	05 Oct 2020 14:18:56

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 09:51'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 12:21'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5c6cac75-dbf4-4e4c-9bd2-dbdf3601d789'	System	05 Oct 2020 18:01:22
User entered 'None (1)'	System	05 Oct 2020 18:01:22

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:07', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5c6cac75-dbf4-4e4c-9bd2-dbdf3601d789'	System	05 Oct 2020 18:01:22
User entered 'No (N)'	System	05 Oct 2020 18:01:22

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:10', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5c6cac75-dbf4-4e4c-9bd2-dbdf3601d789'	System	05 Oct 2020 18:01:22
User entered 'No (N)'	System	05 Oct 2020 18:01:22

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:12', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5c6cac75-dbf4-4e4c-9bd2-dbdf3601d789'	System	05 Oct 2020 18:01:22
User entered 'None (1)'	System	05 Oct 2020 18:01:22

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:14', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '5c6cac75-dbf4-4e4c-9bd2-dbdf3601d789'	System	05 Oct 2020 18:01:22
User entered '05 Oct 2020 14:01'	System	05 Oct 2020 18:01:22

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 13:16'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 2'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:49:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '10cde62a-215e-49b5-b9c9-c3adeaebb7ba'	System	07 Oct 2020 15:50:24
User entered 'None (1)'	System	07 Oct 2020 15:50:24

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:06', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '10cde62a-215e-49b5-b9c9-c3adeaebb7ba'	System	07 Oct 2020 15:50:24
User entered 'No (N)'	System	07 Oct 2020 15:50:24

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:09', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '10cde62a-215e-49b5-b9c9-c3adeaebb7ba'	System	07 Oct 2020 15:50:24
User entered 'No (N)'	System	07 Oct 2020 15:50:24

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '10cde62a-215e-49b5-b9c9-c3adeaebb7ba'	System	07 Oct 2020 15:50:24
User entered 'None (1)'	System	07 Oct 2020 15:50:24

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:21', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '10cde62a-215e-49b5-b9c9-c3adeaebb7ba'	System	07 Oct 2020 15:50:24
User entered '07 Oct 2020 11:50'	System	07 Oct 2020 15:50:24

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 3'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '946def86-02fd-4389-b3ad-c8cf4513a431'	System	08 Oct 2020 14:58:49
User entered 'None (1)'	System	08 Oct 2020 14:58:49

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:39', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '946def86-02fd-4389-b3ad-c8cf4513a431'	System	08 Oct 2020 14:58:49
User entered 'No (N)'	System	08 Oct 2020 14:58:49

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '946def86-02fd-4389-b3ad-c8cf4513a431'	System	08 Oct 2020 14:58:49
User entered 'No (N)'	System	08 Oct 2020 14:58:49

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '946def86-02fd-4389-b3ad-c8cf4513a431'	System	08 Oct 2020 14:58:49
User entered 'None (1)'	System	08 Oct 2020 14:58:49

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:44', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '946def86-02fd-4389-b3ad-c8cf4513a431'	System	08 Oct 2020 14:58:49
User entered '08 Oct 2020 10:58'	System	08 Oct 2020 14:58:49

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 4'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 5'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 6'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:22', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'e7dabf88-b0a9-4055-838f-7f21ae540bb5'	System	10 Oct 2020 17:04:36
User entered 'None (1)'	System	10 Oct 2020 17:04:36

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'e7dabf88-b0a9-4055-838f-7f21ae540bb5'	System	10 Oct 2020 17:04:36
User entered 'No (N)'	System	10 Oct 2020 17:04:36

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:27', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'e7dabf88-b0a9-4055-838f-7f21ae540bb5'	System	10 Oct 2020 17:04:36
User entered 'No (N)'	System	10 Oct 2020 17:04:36

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:29', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'e7dabf88-b0a9-4055-838f-7f21ae540bb5'	System	10 Oct 2020 17:04:36
User entered 'None (1)'	System	10 Oct 2020 17:04:36

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:31', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'e7dabf88-b0a9-4055-838f-7f21ae540bb5'	System	10 Oct 2020 17:04:36
User entered '10 Oct 2020 13:04'	System	10 Oct 2020 17:04:36

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 7'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:01', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd843d344-ffa8-427f-9471-986379e674a4'	System	12 Oct 2020 11:34:19
User entered 'None (1)'	System	12 Oct 2020 11:34:19

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:05', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd843d344-ffa8-427f-9471-986379e674a4'	System	12 Oct 2020 11:34:19
User entered 'No (N)'	System	12 Oct 2020 11:34:19

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd843d344-ffa8-427f-9471-986379e674a4'	System	12 Oct 2020 11:34:19
User entered 'No (N)'	System	12 Oct 2020 11:34:19

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:12', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd843d344-ffa8-427f-9471-986379e674a4'	System	12 Oct 2020 11:34:19
User entered 'None (1)'	System	12 Oct 2020 11:34:19

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:15', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd843d344-ffa8-427f-9471-986379e674a4'	System	12 Oct 2020 11:34:19
User entered '12 Oct 2020 07:34'	System	12 Oct 2020 11:34:19

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:18:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:01', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:05', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:07', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'None (0)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:10', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered 'No (N)'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T10:19:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '0aae9f7e-1d0e-4305-a2f9-eab1ab7e476c'	System	05 Oct 2020 14:19:17
User entered '05 Oct 2020 10:19'	System	05 Oct 2020 14:19:17

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 09:51'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 12:21'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 1, after vaccination (at home)'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71'	System	05 Oct 2020 18:02:08
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71'	System	05 Oct 2020 18:02:08
User entered 'Some interference with activity (2)'	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71'	System	05 Oct 2020 18:02:08
User entered 'Some interference with activity (2)'	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71'	System	05 Oct 2020 18:02:08
User entered 'Some interference with activity (2)'	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71' User entered 'None (0)'	System	05 Oct 2020 18:02:08
	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:55', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71' User entered 'None (0)'	System	05 Oct 2020 18:02:08
	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:01:58', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71'	System	05 Oct 2020 18:02:08
User entered 'No (N)'	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-05T14:02:02', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '03131a77-d476-48d2-b7cb-ca3e5099ec71' User entered '05 Oct 2020 14:02'	System	05 Oct 2020 18:02:08
	System	05 Oct 2020 18:02:08

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '05 Oct 2020 13:16'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 2'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:50:58', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:02', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:05', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:10', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'None (0)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:13', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered 'No (N)'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-07T11:51:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '271bdbd3-5f36-4c9a-b465-e7fec8ca9c86'	System	07 Oct 2020 15:51:21
User entered '07 Oct 2020 11:51'	System	07 Oct 2020 15:51:21

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 3'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:48', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:50', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:51', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:54', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'None (0)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered 'No (N)'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-08T10:58:59', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'd0fe2d3c-066f-4389-9c8f-ad8ff20c8cb9'	System	08 Oct 2020 14:59:04
User entered '08 Oct 2020 10:58'	System	08 Oct 2020 14:59:04

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 4'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '08 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 5'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '09 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 6'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:36', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:42', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:43', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:45', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'None (0)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:47', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered 'No (N)'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-10T13:04:50', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '29db53bd-4efa-4e9d-9913-86bd25413b9e'	System	10 Oct 2020 17:04:52
User entered '10 Oct 2020 13:04'	System	10 Oct 2020 17:04:52

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '10 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	05 Oct 2020 13:58:58
User entered 'Day 7'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:20', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'None (0)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:27', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'No interference with activity (1)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:32', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'No interference with activity (1)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'No interference with activity (1)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:40', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'None (0)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:44', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'None (0)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:48', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered 'No (N)'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-12T07:34:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'da1cde1d-46ca-44ee-a8c9-424886c49fdf'	System	12 Oct 2020 11:34:57
User entered '12 Oct 2020 07:34'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '11 Oct 2020 12:00'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 11:59'	System	05 Oct 2020 13:58:58

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	12 Oct 2020 11:34:57
User entered 'Day 8'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:33:48', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '864dd37d-4fff-4563-b534-1fe07c37eb4a'	System	13 Oct 2020 12:33:56
User entered 'None (0)'	System	13 Oct 2020 12:33:56

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:33:52', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '864dd37d-4fff-4563-b534-1fe07c37eb4a'	System	13 Oct 2020 12:33:56
User entered '13 Oct 2020 08:33'	System	13 Oct 2020 12:33:56

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	12 Oct 2020 11:34:57
User entered 'Day 8'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:33:57', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '018ef4d6-c137-436d-9957-b9fdc0c0d48e'	System	13 Oct 2020 12:34:03
User entered 'None (0)'	System	13 Oct 2020 12:34:03

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:34:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '018ef4d6-c137-436d-9957-b9fdc0c0d48e'	System	13 Oct 2020 12:34:03
User entered '13 Oct 2020 08:34'	System	13 Oct 2020 12:34:03

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	12 Oct 2020 11:34:57
User entered 'Day 8'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:34:04', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '611504f4-7400-434f-8b75-74ff512af931'	System	13 Oct 2020 12:34:10
User entered 'None (0)'	System	13 Oct 2020 12:34:10

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:34:07', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '611504f4-7400-434f-8b75-74ff512af931'	System	13 Oct 2020 12:34:10
User entered '13 Oct 2020 08:34'	System	13 Oct 2020 12:34:10

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	12 Oct 2020 11:34:57
User entered 'Day 8'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:34:12', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c480d547-cd1e-472a-bfde-a3ce793ca628'	System	13 Oct 2020 12:34:17
User entered 'No (N)'	System	13 Oct 2020 12:34:17

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-10-13T08:34:14', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'c480d547-cd1e-472a-bfde-a3ce793ca628'	System	13 Oct 2020 12:34:17
User entered '13 Oct 2020 08:34'	System	13 Oct 2020 12:34:17

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '12 Oct 2020 12:00'	System	12 Oct 2020 11:34:57

US3202375

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:40:59

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
User entered '13 Oct 2020 11:59'	System	12 Oct 2020 11:34:57

US3202375

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	24 Oct 2020 12:48:15

US3202375

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '12 Oct 2020'	(b) (4) zackery harmon (b) (4)	24 Oct 2020 12:48:15
	(b) (4)	

US3202375

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	zackery harmon (b) (4)	24 Oct 2020 12:49:54
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	zackery harmon (b) (4)	24 Oct 2020 12:48:15
	(b) (4)	

US3202375

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty; reason for change Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	24 Oct 2020 12:49:54
User entered 'LVM attempts x3'	(b) (4)	
	zackery harmon (b) (4)	24 Oct 2020 12:48:15
	(b) (4)	

US3202375

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 14:14:17

US3202375

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User entered 'I'	System	19 Oct 2020 14:14:17

US3202375

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 14:14:33

US3202375

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '19 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 14:14:33
	(b) (4)	

US3202375

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 14:14:33

US3202375

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Lilian Nukuna (b) (4)	19 Oct 2020 14:14:33

US3202375

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	19 Oct 2020 14:14:39

US3202375

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User entered 'I'	System	19 Oct 2020 14:14:39

US3202375

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	27 Oct 2020 21:49:47

US3202375

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '27 Oct 2020'	(b) (4) Lilian Nukuna (b) (4)	27 Oct 2020 21:49:47
	(b) (4)	

US3202375

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4)	27 Oct 2020 21:49:47

US3202375

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	Lilian Nukuna (b) (4)	27 Oct 2020 21:49:47

US3202375

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	27 Oct 2020 21:49:54

US3202375

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User entered 'I'	System	27 Oct 2020 21:49:54

US3202375

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:02

US3202375

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '2 Nov 2020' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:25:40
User entered '3 Nov 2020'	Teresa Deese (b) (4)	03 Nov 2020 20:24:02

US3202375

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[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 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:02

US3202375

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'VISIT3'	System	03 Nov 2020 20:24:02

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	03 Nov 2020 20:25:49
User entered '2 Nov 2020' reason for change: Data Entry Error	System	03 Nov 2020 20:25:49
User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	Teresa Deese (b) (4)	03 Nov 2020 20:25:40
User entered '3 Nov 2020'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '14:09'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '2 Nov 2020 14:09'	System	03 Nov 2020 20:25:49
User entered '3 Nov 2020 14:09'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '37.2' C	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Oral (Oral)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '86'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'bpm'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '16'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'breaths/min'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '116'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '75'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'mmHg'	System	03 Nov 2020 20:24:29

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15

US3202375

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15

US3202375

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:34

US3202375

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered empty.	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:24:34

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:48:55
User entered 'No (N)'	Teresa Deese (b) (4)	03 Nov 2020 20:25:31

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User closed query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "Visit 3 Day 57 Immuno 5" sample, as in PPD GCL, it is recorded as collected on "03 NOV 2020", however here in EDC, it is recorded as collected on "02 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Mar 2021 09:11:44
Query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "Visit 3 Day 57 Immuno 5" sample, as in PPD GCL, it is recorded as collected on "03 NOV 2020", however here in EDC, it is recorded as collected on "02 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' answered with 'edc is accurate request put in for change with ppd' (Site from DM).	zackery harmon (b) (4) (b) (4)	09 Mar 2021 19:25:00
User opened query 'Per GCL Lab Recon: Immuno: It appears there is a collection date mismatch between EDC & PPD GCL for this "Visit 3 Day 57 Immuno 5" sample, as in PPD GCL, it is recorded as collected on "03 NOV 2020", however here in EDC, it is recorded as collected on "02 NOV 2020". Please confirm the correct sample collection date in the response, and then please update the correct sample collection date in EDC or Preclarus as necessary. Thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:48:57
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	04 Mar 2021 14:35:10
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		04 Mar 2021 14:35:10

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Signature has been broken.	Teresa Deese (b) (4)	04 Mar 2021 14:35:10
User entered '2 Nov 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	04 Mar 2021 14:35:10
Amendment Manager: User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	17 Feb 2021 01:38:12
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
	(b) (4)	
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 16:41:14
Query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' answered with 'subj returned 03 nov for blood draw after hydrating well' (Site from System).	Teresa Deese (b) (4)	03 Nov 2020 20:49:33
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	03 Nov 2020 20:48:55
User entered '3 Nov 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	03 Nov 2020 20:48:55
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:25:31

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered '14:21' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:48:55
User entered empty.	Teresa Deese (b) (4)	03 Nov 2020 20:25:31

US3202375

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered '2 Nov 2020 14:21'	System	04 Mar 2021 14:35:10
User entered '3 Nov 2020 14:21'	System	03 Nov 2020 20:48:55
User entered empty.	System	03 Nov 2020 20:25:31

US3202375

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:29:43
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	03 Nov 2020 20:25:55

US3202375

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User entered 'I'	System	03 Nov 2020 20:25:55

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 64'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-02T08:18:12', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc2dea27-61e3-44fd-a37f-3c8393b6db69'	System	02 Nov 2020 13:18:22
User entered 'No (N)'	System	02 Nov 2020 13:18:22

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-02T08:18:16', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc2dea27-61e3-44fd-a37f-3c8393b6db69'	System	02 Nov 2020 13:18:22
User entered 'No (N)'	System	02 Nov 2020 13:18:22

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-02T08:18:19', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc2dea27-61e3-44fd-a37f-3c8393b6db69'	System	02 Nov 2020 13:18:22
User entered '02 Nov 2020 08:18:19'	System	02 Nov 2020 13:18:22

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '01 Nov 2020 00:01'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '05 Nov 2020 23:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 71'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T15:59:37', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T15:59:44', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered 'No (N)'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T15:59:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered 'Yes (Y)'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '0'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '0'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '1'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '0'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '0'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:35', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '0'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:41', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:47', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered 'No (N)'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-10T16:00:56', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '96e25246-ef1d-418c-a3a9-bec4c286acf8'	System	10 Nov 2020 21:01:12
User entered '10 Nov 2020 16:00:56'	System	10 Nov 2020 21:01:12

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '08 Nov 2020 00:01'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '12 Nov 2020 23:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered 'Day 78'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-16T08:57:48', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '887178d6-4b31-419c-a57c-c3bf3f051d31'	System	16 Nov 2020 13:58:00
User entered 'No (N)'	System	16 Nov 2020 13:58:00

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-16T08:57:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '887178d6-4b31-419c-a57c-c3bf3f051d31'	System	16 Nov 2020 13:58:00
User entered 'No (N)'	System	16 Nov 2020 13:58:00

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-16T08:57:55', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '887178d6-4b31-419c-a57c-c3bf3f051d31'	System	16 Nov 2020 13:58:00
User entered '16 Nov 2020 08:57:55'	System	16 Nov 2020 13:58:00

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '15 Nov 2020 00:01'	System	01 Sep 2020 15:13:01

US3202375

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:53:20
Data entry locked.	System	01 Sep 2020 15:13:01
User entered '19 Nov 2020 23:59'	System	01 Sep 2020 15:13:01

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-29T09:51:06', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8bae8682-16df-473d-b369-67b3a40fc9fe'	System	29 Nov 2020 14:51:13
User entered 'No (N)'	System	29 Nov 2020 14:51:13

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-29T09:51:08', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8bae8682-16df-473d-b369-67b3a40fc9fe'	System	29 Nov 2020 14:51:13
User entered 'No (N)'	System	29 Nov 2020 14:51:13

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-11-29T09:51:11', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '8bae8682-16df-473d-b369-67b3a40fc9fe'	System	29 Nov 2020 14:51:13
User entered '29 Nov 2020 09:51:11'	System	29 Nov 2020 14:51:13

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-17T08:25:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fad23fa8-7c99-4abb-a1ba-046a5ff70b61'	System	17 Dec 2020 13:25:27
User entered 'No (N)'	System	17 Dec 2020 13:25:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-17T08:25:22', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fad23fa8-7c99-4abb-a1ba-046a5ff70b61'	System	17 Dec 2020 13:25:27
User entered 'No (N)'	System	17 Dec 2020 13:25:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-17T08:25:25', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'fad23fa8-7c99-4abb-a1ba-046a5ff70b61'	System	17 Dec 2020 13:25:27
User entered '17 Dec 2020 08:25:25'	System	17 Dec 2020 13:25:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-27T16:53:15', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128a5494-66f2-4aca-bbbb-cf81fb56dd21'	System	27 Dec 2020 21:53:27
User entered 'No (N)'	System	27 Dec 2020 21:53:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-27T16:53:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128a5494-66f2-4aca-bbbb-cf81fb56dd21'	System	27 Dec 2020 21:53:27
User entered 'No (N)'	System	27 Dec 2020 21:53:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2020-12-27T16:53:24', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '128a5494-66f2-4aca-bbbb-cf81fb56dd21'	System	27 Dec 2020 21:53:27
User entered '27 Dec 2020 16:53:24'	System	27 Dec 2020 21:53:27

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-01-28T16:47:20', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a603832f-6422-45e7-93a1-8cba738151bf'	System	28 Jan 2021 21:47:34
User entered 'No (N)'	System	28 Jan 2021 21:47:34

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-01-28T16:47:23', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a603832f-6422-45e7-93a1-8cba738151bf'	System	28 Jan 2021 21:47:34
User entered 'No (N)'	System	28 Jan 2021 21:47:34

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-01-28T16:47:29', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'a603832f-6422-45e7-93a1-8cba738151bf'	System	28 Jan 2021 21:47:34
User entered '28 Jan 2021 16:47:29'	System	28 Jan 2021 21:47:34

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-02-25T17:33:18', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc9102a0-d505-4a42-bab3-1f654a443ebd'	System	25 Feb 2021 22:34:06
User entered 'No (N)'	System	25 Feb 2021 22:34:06

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-02-25T17:33:44', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc9102a0-d505-4a42-bab3-1f654a443ebd'	System	25 Feb 2021 22:34:06
User entered 'Yes (Y)'	System	25 Feb 2021 22:34:06

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-02-25T17:33:49', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc9102a0-d505-4a42-bab3-1f654a443ebd'	System	25 Feb 2021 22:34:06
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Feb 2021 22:34:06

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-02-25T17:33:53', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'cc9102a0-d505-4a42-bab3-1f654a443ebd'	System	25 Feb 2021 22:34:06
User entered '25 Feb 2021 17:33:53'	System	25 Feb 2021 22:34:06

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:48:19-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'b8b41ca1-325b-4489-a5c0-7540aac222cb' User entered 'No (N)'	System	07 Mar 2021 23:49:03

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:48:39-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'b8b41ca1-325b-4489-a5c0-7540aac222cb' User entered 'Yes (Y)'	System	07 Mar 2021 23:49:03
	System	07 Mar 2021 23:49:03

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:48:45-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'b8b41ca1-325b-4489-a5c0-7540aac222cb'	System	07 Mar 2021 23:49:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Mar 2021 23:49:03

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:48:49-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'b8b41ca1-325b-4489-a5c0-7540aac222cb' User entered '07 Mar 2021 18:48:49'	System	07 Mar 2021 23:49:03
	System	07 Mar 2021 23:49:03

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-12T10:15:57-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '65f0ae46-98d7-411d-b7da-9b82fc6580fa'	System	12 Mar 2021 15:16:17
User entered 'No (N)'	System	12 Mar 2021 15:16:17

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-12T10:16:02-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '65f0ae46-98d7-411d-b7da-9b82fc6580fa'	System	12 Mar 2021 15:16:17
User entered 'No (N)'	System	12 Mar 2021 15:16:17

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-12T10:16:10-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '65f0ae46-98d7-411d-b7da-9b82fc6580fa' User entered '12 Mar 2021 10:16:10'	System	12 Mar 2021 15:16:17
	System	12 Mar 2021 15:16:17

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-22T14:21:54-04:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '246007c7-cfd3-466e-a40f-afb0573e408f' User entered 'No (N)'	System	22 Mar 2021 18:22:08
	System	22 Mar 2021 18:22:08

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-22T14:22:01-04:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '246007c7-cfd3-466e-a40f-afb0573e408f' User entered 'No (N)'	System	22 Mar 2021 18:22:08
	System	22 Mar 2021 18:22:08

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-22T14:22:04-04:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: '246007c7-cfd3-466e-a40f-afb0573e408f' User entered '22 Mar 2021 14:22:04'	System	22 Mar 2021 18:22:08
	System	22 Mar 2021 18:22:08

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Have you been exposed to someone with 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Please 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)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 21:33:40

US3202375

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:40:59

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:33:40
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 21:33:40

US3202375

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:59

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:48:59-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'be9403c6-ce31-4279-aa4d-16492ee9d358'	System	07 Mar 2021 23:49:10
User entered 'No (N)'	System	07 Mar 2021 23:49:10

US3202375

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:40:59

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2b232e98d47acb43)', Time: '2021-03-07T18:49:06-05:00', User OID: 'PatientReportedOutcome (US3202375)', ODM File OID: 'be9403c6-ce31-4279-aa4d-16492ee9d358'	System	07 Mar 2021 23:49:10
User entered '07 Mar 2021 18:49:06'	System	07 Mar 2021 23:49:10

US3202375

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Nov 2020 17:34:02

US3202375

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User entered '30 Nov 2020'	(b) (4) zackery harmon (b) (4)	30 Nov 2020 17:34:02
	(b) (4)	

US3202375

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Nov 2020 17:34:02

US3202375

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:58:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Nov 2020 17:34:02
	(b) (4)	

US3202375

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:54:19
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Nov 2020 17:34:19

US3202375

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:53:13
User entered 'I'	System	30 Nov 2020 17:34:19

US3202375

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	04 Jan 2021 18:27:39

US3202375

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '4 Jan 2021'	Lilian Nukuna (b) (4)	04 Jan 2021 18:27:39

US3202375

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	04 Jan 2021 18:27:39

US3202375

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	Lilian Nukuna (b) (4)	04 Jan 2021 18:27:39

US3202375

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	04 Jan 2021 18:27:44

US3202375

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User entered 'I'	System	04 Jan 2021 18:27:44

US3202375

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 22:21:19

US3202375

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 22:21:19

US3202375

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 22:21:19

US3202375

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	08 Mar 2021 22:21:19

US3202375

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	04 Mar 2021 19:50:32

US3202375

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User entered 'I'	System	04 Mar 2021 19:50:32

US3202375

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	04 Mar 2021 19:50:59

US3202375

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '4 Mar 2021'	Lilian Nukuna (b) (4)	04 Mar 2021 19:50:59

US3202375

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4)	04 Mar 2021 19:50:59

US3202375

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:40:59

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'left a voice message'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	04 Mar 2021 19:50:59

US3202375

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4)	04 Mar 2021 19:51:06

US3202375

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:16:38
User entered 'I'	System	04 Mar 2021 19:51:06

US3202375

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:01

US3202375

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '31 Mar 2021'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:01

US3202375

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[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 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:01

US3202375

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered 'VISIT4'	System	31 Mar 2021 15:37:01

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	31 Mar 2021 15:37:07

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:14

US3202375

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered empty.	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:14

US3202375

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:31

US3202375

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '31 Mar 2021'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:31

US3202375

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '11:11'	(b) (4) Teresa Deese (b) (4)	31 Mar 2021 15:37:31

US3202375

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '31 Mar 2021 11:11'	System	31 Mar 2021 15:37:31

US3202375

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:45:45
User entered 'Yes (Y)'	Teresa Deese (b) (4)	31 Mar 2021 15:38:43

US3202375

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:40:59

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	05 Apr 2021 19:45:45
User entered 'I'	System	31 Mar 2021 15:38:43

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:09
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11:25'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:30:09

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:31
User entered '11 Nov 2020 11:25'	System	11 Nov 2020 20:30:09

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:09

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:31
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:09

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 1 (Day 1)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '09 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	11 Nov 2020 20:30:56

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '101.6' F	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:30:56
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 2 (Day 2)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '10 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	11 Nov 2020 20:31:30

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98.6' F	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:31:30
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 3 (Day 3)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	11 Nov 2020 20:32:10

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '37.0' C	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:10

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:10

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:10

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:10
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 4 (Day 4)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '12 Nov 2020'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	12 Nov 2020 18:54:49

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per CDM: It appears temperature of 994.4 F is rather high. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:09:42
Query 'Per CDM: It appears temperature of 994.4 F is rather high. Please review and update accordingly.' answered with 'UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	20 Jan 2021 22:21:54
User entered '99.4' F reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Jan 2021 22:21:50
User opened query 'Per CDM: It appears temperature of 994.4 F is rather high. Please review and update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 21:00:00
User entered '994.4' F	zackery harmon (b) (4) (b) (4)	12 Nov 2020 18:54:49

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) zackery harmon (b) (4)	12 Nov 2020 18:54:49
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 5 (Day 5)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '13 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	13 Nov 2020 19:06:41

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99.2' F	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Nov 2020 19:06:41

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 6 (Day 6)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '14 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99.0' F	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:34:13

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 7 (Day 7)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '15 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99.0' F	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:08

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 8 (Day 8)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '16 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99.1' F	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	16 Nov 2020 19:35:54

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 9 (Day 9)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '17 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

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Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99.4' F	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:25:01

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 10 (Day 10)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '18 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98.9' F	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	18 Nov 2020 20:12:04

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 11 (Day 11)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '19 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User entered '%'	System	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '98.6' F	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:39
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	19 Nov 2020 20:20:59

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:29
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 00:39:27
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Nov 2020 20:33:07
Query 'Data is required. Please complete.' answered with 'results not in yet' (Site from System).	zackery harmon (b) (4)	11 Nov 2020 20:32:34
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4) System	11 Nov 2020 20:32:29
User entered empty.	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01NOV2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Feb 2021 11:23:15
Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01NOV2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' answered with 'swab was done on 11 nov with results in chart' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:20:29
User entered '11 Nov 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 21:20:14
User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 01NOV2020 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and provide both Accession number and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 11:55:00
User entered '1 Nov 2020'	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:29
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[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)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:32:29
	(b) (4)	

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:32:29

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:46
User entered '0'	System	19 Nov 2020 20:33:07

US3202375

Folder: Covid-19 Assessment 11 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:40:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:52
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 14:36:05

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:16:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:52:30

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:16:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '10:54'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:52:30

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:16:58
User entered '30 Sep 2020 10:54'	System	02 Oct 2020 12:52:30

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:40:59

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:16:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:52:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID-19 Contact

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[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:16:58
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:52:30

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 1 (Day 1)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '26 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered empty.	System	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:19

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 2 (Day 2)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '27 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered empty.	System	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:43

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 3 (Day 3)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '28 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered empty.	System	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:53:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 4 (Day 4)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '29 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered empty.	System	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:54:15

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 5 (Day 5)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per CDM: It appears that O2 Saturation is not recorded for Days 5 and Temperature for Days 6. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 13:08:49
Query 'Per CDM: It appears that O2 Saturation is not recorded for Days 5 and Temperature for Days 6. If not collected, please consider recording these as NOT DONE' answered with 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	20 Jan 2021 22:41:17
User entered missing code ND - Not Done; reason for change Data Entry Error	Erica Osmundsen (b) (4)	20 Jan 2021 22:41:11
User opened query 'Per CDM: It appears that O2 Saturation is not recorded for Days 5 and Temperature for Days 6. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 17:14:59
User entered empty.	Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered '%'	System	20 Jan 2021 22:41:11
User entered empty.	System	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '36.6' C	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:08:25
User entered 'None (None)'	Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Moderate (Moderate)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 12:58:51

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Day 6 (Day 6)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '1 Oct 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '99'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User entered '%'	System	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per CDM: It appears that 'Temperature' is not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:14:19
Query 'Per CDM: It appears that 'Temperature' is not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:18:37
User entered missing code ND - Not Done; reason for change Data Entry Error	Teresa Deese (b) (4)	01 Feb 2021 21:18:31
User opened query 'Per CDM: It appears that 'Temperature' is not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 13:09:11
User entered empty.	Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'None (None)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:40:59

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:06
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Mild (Mild)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:03:09

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

Was the Subject Tested For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 13:03:04
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:58
Query 'Data is required. Please complete.' answered with 'pending result' (Site from System).	Erica Osmundsen (b) (4)	02 Oct 2020 13:05:26
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 13:05:21
User entered empty.	Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[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)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

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Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	02 Oct 2020 13:05:21

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:40:59

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:12
User entered '0'	System	11 Nov 2020 20:36:58

US3202375

Folder: Covid-19 Assessment 30 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:40:59

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 03:17:23
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	11 Dec 2020 14:35:56

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 02:00:46
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' answered with 'THOSE WERE COLLECTED FOR CONVALESCENT PERIOD 2 AND ARE RECORDED UNDER THE SALIVA COLLECTION ECRF FOR iLLNESS vISIT (2) IN EDC' (Site from DM).	Erica Osmundsen (b) (4)	30 Nov 2020 18:27:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 01:07:14
User accepted default value 'Day 3 (Day 3)'	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:39

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 5 (Day 5)'	zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:39

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 7 (Day 7)'	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:39

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 9 (Day 9)'	zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:39

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 14 (Day 14)'	zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 21 (Day 21)'	zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 28 (Day 28)'	zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:39
	(b) (4)	

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 3 (Day 3)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '13 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 5 (Day 5)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 04:55:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'Date it was received by central lab shipping these are the dates that are collected. ' (Site from DM).	zackery harmon (b) (4) (b) (4)	02 Dec 2020 19:12:26
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 16NOV2020 and 18NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 02:00:43
User entered '15 Nov 2020'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 7 (Day 7)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same 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)	02 Feb 2021 07:19:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same 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 'check with lab; results are in chart for saliva day 7' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:21:24
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 17NOV2020 is recorded under Illness Visit Day 7 in EDC, however the same 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)	07 Dec 2020 07:18:04
User entered '17 Nov 2020'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 9 (Day 9)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 14 (Day 14)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 21 (Day 21)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User accepted default value 'Day 28 (Day 28)'	Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	17 Nov 2020 18:26:05

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:57

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:57
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Clinic (Clinic)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:57
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'SICKD1'	System	11 Nov 2020 20:34:57

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11:00'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered '30 Sep 2020 11:00'	System	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30
DataPoint set to visible.	(b) (4) System	11 Nov 2020 20:33:45

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered missing code ND - Not Done.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30
DataPoint set to visible.	(b) (4) System	11 Nov 2020 20:33:45

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '36.6' C	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '70'	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'bpm'	System	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '12'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'breaths/min'	System	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '103'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'mmHg'	System	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '65'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'mmHg'	System	11 Nov 2020 20:35:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:37

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:37
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:40:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:43

US3202375

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '30 Sep 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:35:43
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:33:45
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:33:45
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Clinic (Clinic)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:33:45
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'SICKD1'	System	11 Nov 2020 20:33:45

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11:30'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered '11 Nov 2020 11:30'	System	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '64' in	(b) (4)	
	zackery harmon (b) (4)	11 Nov 2020 20:34:24
DataPoint set to visible.	(b) (4)	
	System	11 Nov 2020 20:33:45

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '157.0' kg	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24
DataPoint set to visible.	(b) (4) System	11 Nov 2020 20:33:45

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '37.0' C	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Oral (Oral)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '74'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'bpm'	System	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '16'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'breaths/min'	System	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '120'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'mmHg'	System	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '86'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User entered 'mmHg'	System	11 Nov 2020 20:34:24

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55

US3202375

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:30

US3202375

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:30
	(b) (4)	

US3202375

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:40:59

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:37

US3202375

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:26:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '11 Nov 2020'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:34:37
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:15
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:15
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[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 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:15
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered 'SICKD28'	System	11 Nov 2020 20:36:15

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:17
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	11 Nov 2020 20:36:17

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:40:59

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:20
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:40:59

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:20
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:40:59

[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 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:23
	(b) (4)	

US3202375

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 09 Jun 2021 15:40:59

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	11 Nov 2020 20:36:23

US3202375

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:24:55

US3202375

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:24:55

US3202375

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:24:55

US3202375

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

Form: Visit Date

Generated On: 09 Jun 2021 15:40:59

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 21:24:55

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:03:35
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	22 Apr 2021 16:13:55
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:12

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User closed query 'Per IRT system use and date: This subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 14:21:09
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:03:35
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 'DONE' (Site from DM).	Erica Osmundsen (b) (4)	22 Apr 2021 16:14:14
User entered 'Amendment 6 or later (Amendment 6 or later)'	Erica Osmundsen (b) (4)	22 Apr 2021 16:13:55
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)	22 Apr 2021 09:24:45
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:10:12

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User entered empty.	System	01 Feb 2021 21:25:25

US3202375

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

Form: Unblinding

Generated On: 09 Jun 2021 15:40:59

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User entered empty.	System	01 Feb 2021 21:25:25

US3202375

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:26

US3202375

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:26

US3202375

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '10:50'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:26

US3202375

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:40:59

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User entered '1 Feb 2021 10:50'	System	01 Feb 2021 21:27:26

US3202375

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:59

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:35

US3202375

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:59

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '1 Feb 2021'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:35

US3202375

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:59

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '10:48'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:27:35

US3202375

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:40:59

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:57:07
User entered '1 Feb 2021 10:48'	System	01 Feb 2021 21:27:35

US3202375

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:40:59

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:16:56
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:17:58
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	zackery harmon (b) (4)	30 Sep 2020 17:50:34
User entered 'No (N)'	(b) (4)	
	zackery harmon (b) (4)	12 Sep 2020 14:02:16
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:54:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:54:55
Data point term sent to Coder	System	13 Apr 2021 16:56:50
DataPoint Un-verified.	Erica Osmundsen (b) (4)	13 Apr 2021 16:56:38
Coding entries removed.	Erica Osmundsen (b) (4)	13 Apr 2021 16:56:38
Signature has been broken.	Erica Osmundsen (b) (4)	13 Apr 2021 16:56:38
User entered 'Upper respiratory infection of unknown cause' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	13 Apr 2021 16:56:38
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:15:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Feb 2021 21:15:49
Data point term sent to Coder	System	01 Feb 2021 21:14:30
User entered 'URI'	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '28 Sep 2020'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
User entered empty.	System	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '30 Sep 2020'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
User entered empty.	System	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered 'l'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered '0'	(b) (4) Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Feb 2021 21:13:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Teresa Deese (b) (4)	01 Feb 2021 21:13:54
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Feb 2021 21:13:42
User entered empty.	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:17:45
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
User entered '0'	System	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24
User entered 'I'	System	01 Feb 2021 21:13:42

US3202375

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 15:40:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:24

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:41
User entered 'USA-US128-2021-mRNA-1273-P301000016'	System	06 Apr 2021 18:57:37
User entered 'New'	(b) (4), (b) (6)	06 Apr 2021 18:57:37

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User closed query 'PV Query: As the death certificate copy is listed as "pending investigation". Please update the event term to the underlying cause of death once available.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 16:56:46
Query 'PV Query: As the death certificate copy is listed as "pending investigation". Please update the event term to the underlying cause of death once available.' answered with 'this is very unlikely to be updated. Subject's body was cremated before an autopsy was performed' (Site from Safety).	Teresa Deese (b) (4)	23 Apr 2021 14:07:21
User opened query 'PV Query: As the death certificate copy is listed as "pending investigation". Please update the event term to the underlying cause of death once available.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 22:51:01
User closed query 'PV Query: Please update the event term to the underlying cause of death once available.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:57:23
Query 'PV Query: Please update the event term to the underlying cause of death once available.' answered with 'presumed to be abdominal aortic aneurysm or cardiac arrest, but not confirmed' (Site from Safety).	Erica Osmundsen (b) (4)	14 Apr 2021 14:19:53
User opened query 'PV Query: Please update the event term to the underlying cause of death once available.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:41:39
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User coded data point as SOC: General disorders and administration site conditions, HLT: Fatal outcomes, HLT: Death and sudden death, PT: Sudden death, LLT: Sudden death, cause unknown - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:33:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	06 Apr 2021 12:33:53
Data point term sent to Coder	System	05 Apr 2021 19:10:27
User entered 'SUDDEN DEATH (UNKNOWN CAUSE)'	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:02:30
DataPoint Un-verified.	(b) (4)	
	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:30
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:30
User entered '04 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '02 Apr 2021'	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:02:30
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	23 Apr 2021 15:38:42
	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:42
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:42
User entered '04 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:42
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	23 Apr 2021 15:38:30
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
	(b) (4)	
User entered '02 Apr 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Grade 4 (Grade 4)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'l'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'l'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

US3202375

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Fatal (FATAL)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:09:48

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4)	05 Apr 2021 19:09:48

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:02:30
User closed query 'PV Query: Thanks for providing the details that, autopsy was not done prior to cremation. Please update EDC accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:56:54
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:10:13

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Folder: Adverse Events

Form: Adverse Events (10)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'UPDATE23APR21--MEDICAL EXAMINER CONTACTED ON 23APR21 AND CONFIRMED THAT NO UPDATED CAUSE OF DEATH LISTED YET--WILL SEND TO SITE WHEN UPDATED INFORMATION/FINAL CAUSE ENTERED. SUBJECT'S DATE OF DEATH UPDATED PER DEATH CERTIFICATE (WAS ORIGINALLY NOTED AS 02APR2021 DUE TO MISCOMMUNICATION BETWEEN GRIEVING FAMILY AND SITE STAFF ON DATE FIRST REPORTED. JUST NOTICED THAT ACTUAL DATE OF DEATH WAS 04APR2021.-UPDATE--SUBJECT'S BODY CREMATED PRIOR TO AUTOPSY BECAUSE FAMILY THOUGHT THAT THE AUTOPSY WAS COMPLETE WHEN BODY WAS RELEASED. TOXICOLOGY NEGATIVE AND FOUL PLAY WAS RULED OUT PER HUSBAND WITH PROBABLE CAUSE OF DEATH CARDIAC ARREST OR ABDOMINAL AORTIC ANEURYSM BUT NEITHER CONFIRMED. CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT. SUBJECT WAS DISCOVERED BY FAMILY MEMBER DECEASED WITH NO KNOWN PREEXISTING ILLNESS. SUBJECT HAD COMPLAINED OF NAUSEA AND FEELING ILL A BIT EARLIER SO WENT TO BED AND WAS LATER FOUND DECEASED. STILL AWAITING AUTOPSY RESULTS AND FAMILY REPORTED STILL NO KNOWN CAUSE OF DEATH WHEN F/UP CALL PLACED ON 09APR2021' reason for change: Data Entry Error DataPoint Un-verified.	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	23 Apr 2021 15:56:35
	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	23 Apr 2021 15:40:28
Signature has been broken.	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	23 Apr 2021 15:40:28

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Folder: Adverse Events

Form: Adverse Events (10)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'UPDATE23APR21--SUBJECT'S DATE OF DEATH UPDATED PER DEATH CERTIFICATE (WAS ORIGINALLY NOTED AS 02APR2021 DUE TO MISCOMMUNICATION BETWEEN GRIEVING FAMILY AND SITE STAFF ON DATE FIRST REPORTED. JUST NOTICED THAT ACTUAL DATE OF DEATH WAS 04APR2021.-UPDATE--SUBJECT'S BODY CREMATED PRIOR TO AUTOPSY BECAUSE FAMILY THOUGHT THAT THE AUTOPSY WAS COMPLETE WHEN BODY WAS RELEASED. TOXICOLOGY NEGATIVE AND FOUL PLAY WAS RULED OUT PER HUSBAND WITH PROBABLE CAUSE OF DEATH CARDIAC ARREST OR ABDOMINAL AORTIC ANEURYSM BUT NEITHER CONFIRMED. CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT. SUBJECT WAS DISCOVERED BY FAMILY MEMBER DECEASED WITH NO KNOWN PREEXISTING ILLNESS. SUBJECT HAD COMPLAINED OF NAUSEA AND FEELING ILL A BIT EARLIER SO WENT TO BED AND WAS LATER FOUND DECEASED. STILL AWAITING AUTOPSY RESULTS AND FAMILY REPORTED STILL NO KNOWN CAUSE OF DEATH WHEN F/UP CALL PLACED ON 09APR2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:40:28
Query 'PV Query: Thanks for providing the details that, autopsy was not done prior to cremation. Please update EDC accordingly.' answered with 'update edc where? not sure what you want' (Site from Safety).	Teresa Deese (b) (4)	23 Apr 2021 14:17:16
User opened query 'PV Query: Thanks for providing the details that, autopsy was not done prior to cremation. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 22:50:32
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:57:40
	(b) (4), (b) (6)	15 Apr 2021 14:16:20
User entered '-UPDATE--SUBJECT'S BODY CREMATED PRIOR TO AUTOPSY BECAUSE FAMILY THOUGHT THAT THE AUTOPSY WAS COMPLETE WHEN BODY WAS RELEASED. TOXICOLOGY NEGATIVE AND FOUL PLAY WAS RULED OUT PER HUSBAND WITH PROBABLE CAUSE OF DEATH CARDIAC ARREST OR ABDOMINAL AORTIC ANEURYSM BUT NEITHER CONFIRMED. CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT. SUBJECT WAS DISCOVERED BY FAMILY MEMBER DECEASED WITH NO KNOWN PREEXISTING ILLNESS. SUBJECT HAD COMPLAINED OF NAUSEA AND FEELING ILL A BIT EARLIER SO WENT TO BED AND WAS LATER FOUND DECEASED. STILL AWAITING AUTOPSY RESULTS AND FAMILY REPORTED STILL NO KNOWN CAUSE OF DEATH WHEN F/UP CALL PLACED ON 09APR2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Apr 2021 14:31:00

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Folder: Adverse Events

Form: Adverse Events (10)

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[Narrative](#)

Audit	User	Time (GMT)
User entered '-UPDATE--SUBJECT'S BODY CREMATED PRIOR TO AUTOPSY BECAUSE FAMILY THOUGHT THAT THE AUTOPSY WAS COMPLETE WHEN BODY WAS RELEASED. TOXICOLOGY NEGATIVE AND FOUL PLAY WAS RULED OUT PER HUSBAND WITH PROBABLY CAUSE OF DEATH CARDIAC ARREST OR ABDOMINAL AORTIC ANEURYSM BUT NEITHER CONFIRMED. CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT. SUBJECT WAS DISCOVERED BY FAMILY MEMBER DECEASED WITH NO KNOWN PREEXISTING ILLNESS. SUBJECT HAD COMPLAINED OF NAUSEA AND FEELING ILL A BIT EARLIER SO WENT TO BED AND WAS LATER FOUND DECEASED. STILL AWAITING AUTOPSY RESULTS AND FAMILY REPORTED STILL NO KNOWN CAUSE OF DEATH WHEN F/UP CALL PLACED ON 09APR2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	14 Apr 2021 14:24:02
Query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' answered with 'Spouse contacted site today and stated that body was released so family proceeded with cremation assuming autopsy had been completed when it had not. death certificate copy given to site with cause of death listed as "PENDING INVESTIGATION"' (Site from Safety).	Erica Osmundsen (b) (4)	14 Apr 2021 14:22:17
User closed query 'per source notes subject was discovered deceased with no known preexisting illness, please confirm and add to narrative.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:09:49
User opened query 'PV Query: Please provide autopsy results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342, if performed. If not performed, please state so. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 12:42:02

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EAB) (1725)

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Query 'per source notes subject was discovered deceased with no known preexisting illness, please confirm and add to narrative.' answered with 'UPDATED' (Site from CRA). Signature has been broken.	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	09 Apr 2021 21:19:12
	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	09 Apr 2021 21:16:32
User entered 'CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT. SUBJECT WAS DISCOVERED BY FAMILY MEMBER DECEASED WITH NO KNOWN PREEXISTING ILLNESS. SUBJECT HAD COMPLAINED OF NAUSEA AND FEELING ILL A BIT EARLIER SO WENT TO BED AND WAS LATER FOUND DECEASED. STILL AWAITING AUTOPSY RESULTS AND FAMILY REPORTED STILL NO KNOWN CAUSE OF DEATH WHEN F/UP CALL PLACED ON 09APR2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	09 Apr 2021 21:16:32
User opened query 'per source notes subject was discovered deceased with no known preexisting illness, please confirm and add to narrative.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6) [REDACTED]	09 Apr 2021 19:48:03
	(b) (4), (b) (6) [REDACTED]	09 Apr 2021 19:46:47
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	09 Apr 2021 19:46:01
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:10:17
User entered 'CAUSE OF DEATH NOT YET KNOWN--SUBJECT'S SPOUSE REPORTED DEATH TO SITE ON 05APR2021. AWAITING AUTOPSY REPORT.'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	05 Apr 2021 19:09:48

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Folder: Adverse Events

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Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered 'I'	System	05 Apr 2021 19:09:48

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered 'I'	System	05 Apr 2021 19:09:48

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 15:40:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

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Folder: Adverse Events

Form: Adverse Events (11)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26

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Folder: Adverse Events

Form: Adverse Events (11)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:55:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	13 Apr 2021 17:55:02
Data point term sent to Coder	System	13 Apr 2021 16:58:51
User entered 'upper respiratory infection of unknown cause'	Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '09 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User entered empty.	System	13 Apr 2021 16:58:15

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '20 Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User entered empty.	System	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Not Related (NOT RELATED)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'I'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Form: Adverse Events (11)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'illness visit completed on 11NOV2020 and results of COVID-19 test were negative'	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:15

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User entered '0'	System	13 Apr 2021 16:58:15

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26
User entered '1'	System	13 Apr 2021 16:58:15

US3202375

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 15:40:59

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:23:26

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per CDM: Response noted however, the CM #1 is recorded with an indication of 'SORE THROAT, FEVER'? There is no corresponding Conmed recorded that matches Diary Dose 2 Day 1, 'Headache' in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify further. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:13:28
Query 'Per CDM: Response noted however, the CM #1 is recorded with an indication of 'SORE THROAT, FEVER'? There is no corresponding Conmed recorded that matches Diary Dose 2 Day 1, 'Headache' in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify further. ' answered with 'tylenol was for an AE. don't see where any Rx were indicated in diary dose 2 day1' (Site from DM).	Teresa Deese (b) (4)	01 Feb 2021 21:24:32
User opened query 'Per CDM: Response noted however, the CM #1 is recorded with an indication of 'SORE THROAT, FEVER'? There is no corresponding Conmed recorded that matches Diary Dose 2 Day 1, 'Headache' in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify further. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:36:08
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 13:36:08

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'OTC MEDS SUBJECT USED WAS PREVIOUSLY RECORDED IN CONMEDS. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 21:15:34
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 11:05:55
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	30 Sep 2020 18:03:43
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	12 Sep 2020 14:01:33
User entered 'Yes (Y)'	zackery harmon (b) (4)	12 Sep 2020 14:01:17

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:55:18
Data point term sent to Coder	System	13 Apr 2021 16:59:53
Coding entries removed.	Erica Osmundsen (b) (4) (b) (4)	13 Apr 2021 16:58:53
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	09 Apr 2021 16:10:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:06:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 18:06:31
Data point term sent to Coder	System	30 Sep 2020 18:04:25
User entered 'TYlenol'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:04:22

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
Signature has been broken.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User entered 'upper respiratory infection of unknown cause' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Sore throat, fever'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '500'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22

US3202375

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'mg (mg)'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'as needed (PRN)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Oral (ORAL)'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '28 Sep 2020'	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '0'	(b) (4) zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
Signature has been broken.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AEs have resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Dec 2020 19:37:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AEs have resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'Currently still taking med' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 14:17:16
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AEs have resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 13:09:52
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
Signature has been broken.	(b) (4) Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User entered '20 Nov 2020' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	13 Apr 2021 16:58:53
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) zackery harmon (b) (4)	30 Sep 2020 18:04:22
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' answered with 'done' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) Teresa Deese (b) (4)	17 Nov 2020 07:36:39 03 Nov 2020 20:50:53
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol 8.3.4. Review and update entry as appropriate.' (Site from DM). User entered 'Yes (Y)'	Teresa Deese (b) (4) (b) (4), (b) (6) zackery harmon (b) (4)	03 Nov 2020 20:50:44 29 Oct 2020 09:43:23 30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	30 Sep 2020 18:04:22

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:40:59

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered empty.	System	30 Sep 2020 18:04:22

US3202375

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:40:59

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	12 Sep 2020 14:02:05
	(b) (4)	

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

Date of study discontinuation/completion (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:06:10
DataPoint Un-verified.	(b) (4)	
	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:08
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:08
User entered '4 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:38:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
	(b) (4)	
User closed query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	05 Apr 2021 19:45:25
User entered '2 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	05 Apr 2021 19:45:25
User opened query 'Date of Study Discontinuation/Completion is after Date of Death. Please correct.' (Site from System).	System	05 Apr 2021 19:38:17
User entered '5 Apr 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Death (DEATH)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:03:35
User closed query 'Per CDM: Per CCGs and entry of "Sudden Death" as an AE, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 13:55:06
Query 'Per CDM: Per CCGs and entry of "Sudden Death" as an AE, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' answered with 'updated' (Site from DM).	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:27
DataPoint Un-verified.	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
Signature has been broken.	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
User opened query 'Per CDM: Per CCGs and entry of "Sudden Death" as an AE, Cause of death needs to be updated to "Adverse Event". Please confirm and amend.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:26:34
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Unknown (UNKNOWN)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

Date of death (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:06:10
User closed query 'Reason for study discontinuation is Death, however Date of death is after Date of study discontinuation. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 15:38:08
Query 'Reason for study discontinuation is Death, however Date of death is after Date of study discontinuation. Please correct.' answered by data change (Site from System).	System	23 Apr 2021 15:38:08
User opened query 'Reason for study discontinuation is Death, however Date of death is after Date of study discontinuation. Please correct.' (Site from System).	System	23 Apr 2021 15:37:57
DataPoint Un-verified.	Erica Osmundsen (b) (4)	23 Apr 2021 15:37:57
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:37:57
User entered '04 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:37:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered '2 Apr 2021' reason for change: Data Entry Error	(b) (4)	05 Apr 2021 19:38:17
User entered '5 Apr 2021'	Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:40:59

[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:34:06
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 18:03:35
DataPoint Un-verified.	(b) (4) Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
Signature has been broken.	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Apr 2021 00:33:00
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:11:38
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:17
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	05 Apr 2021 19:37:50

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'USA-US128-2021-MRNA-1273-P301000016'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Mark'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'McKenzie'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'US'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '4'	System	26 Apr 2021 16:58:43
User entered '3'	System	15 Apr 2021 15:58:05
User entered '2'	System	12 Apr 2021 18:57:33
User entered '1'	System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'USA-US128-2021-MRNA-1273-P301000016'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Mark'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'McKenzie'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'US'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '4'	System	26 Apr 2021 16:58:43
User entered '3'	System	15 Apr 2021 15:58:05
User entered '2'	System	12 Apr 2021 18:57:33
User entered '1'	System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered '06/Apr/2021 13:58'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:40:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'USA-US128-2021-MRNA-1273-P301000016'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Mark'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'McKenzie'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'US'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '4'	System	26 Apr 2021 16:58:43
User entered '3'	System	15 Apr 2021 15:58:05
User entered '2'	System	12 Apr 2021 18:57:33
User entered '1'	System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:40:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:16:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:09
User entered '12/Apr/2021 14:57'	(b) (4) System	12 Apr 2021 18:57:33

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:40:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 14:16:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Apr 2021 15:35:09
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 18:57:33

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'USA-US128-2021-MRNA-1273-P301000016'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Mark'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'McKenzie'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Site Address: [Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'US'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '4'	System	26 Apr 2021 16:58:43
User entered '3'	System	15 Apr 2021 15:58:05
User entered '2'	System	12 Apr 2021 18:57:33
User entered '1'	System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:40:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:10:33
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered '15/Apr/2021 11:58'	(b) (4) System	15 Apr 2021 15:58:05

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:40:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:10:33
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:23:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:05

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'USA-US128-2021-MRNA-1273-P301000016'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Yes (Y)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'No (N)'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'Mark'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 18:57:47
User entered 'McKenzie'	System	06 Apr 2021 18:57:37

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: City](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 18:57:09
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 19:46:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 16:10:37
User entered 'US'	(b) (4) System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 15:40:59

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User entered '4'	System	26 Apr 2021 16:58:43
User entered '3'	System	15 Apr 2021 15:58:05
User entered '2'	System	12 Apr 2021 18:57:33
User entered '1'	System	06 Apr 2021 18:58:08

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:40:59

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:06:10
User entered '26/Apr/2021 12:58'	(b) (4) System	26 Apr 2021 16:58:43

US3202375

Folder: SAE USA-US128-2021-MRNA-1273-P301000016

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:40:59

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 13:44:21
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:06:10
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 16:58:43