

US3812060 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:52:46

All time stamps listed in this document are displayed in GMT

US3812060

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Participant ID

US3812060

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

US3812060

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Date of Birth (MMM yyyy)	(b) (6) 1958
Age	62
Age Units	YEARS
Age (Derived)	62
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Date of Informed Consent (dd MMM yyyy) 06 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 19:35:07

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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) 20 Feb 2021 19:35:07

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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) 20 Feb 2021 19:35:07

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Condition	LEFT SIDE INGUINAL HERNIA OPERATION
Start date (dd MMM yyyy)	UN UNK 1966
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1966
Start Year (derived)	1966
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Condition	LEFT SIDE INGUINAL HERNIA
Start date (dd MMM yyyy)	(b) (6) 1958
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1966
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1958
Start Year (derived)	1958
Stop Month and Year (derived)	JAN 1966
Stop Year (derived)	1966

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1967
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1967
Start Year (derived)	1967
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Condition	TINNITIS
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Condition	PRESBYCUSIS BOTH SIDE
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Condition	TUBULAR ADENOMA OF COLON
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	06 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:59
Height (<i>xxx.x</i>)	68.0 in
Weight (<i>xxx.x</i>)	174 lb
BMI (<i>xxx.x</i>)	26.51193 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
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) 20 Feb 2021 19:35:07

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

06 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:07

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:07

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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	True
Specify	ROUTINE GYM ACTIVITY 5X WEEK AND INTERACTS WITH 5 OR MORE PEOPLE

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	06 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

What was the date of randomization? (dd MMM yyyy) 06 AUG 2020

What was the participant's randomization number? 101558

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

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) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 09:59
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	06 AUG 2020
Time of assessment (00:00-23:59)	12:12 (24 HR)
Vital Signs Date and Time (derived)	06 AUG 2020 12:12
Temperature (xxx.x)	97.4 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 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)	76 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

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) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

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) 06 AUG 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 06 AUG 2020 11:40

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) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	06 AUG 2020
Collection time (00:00-23:59)	11:34 (24 HR)
Collection date and time (derived)	06 AUG 2020 11:34

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)			06 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:37	06 AUG 2020 11:37
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

97.4 °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 AUG 2020 12:16

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 14:30

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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 98.0 °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	06 AUG 2020 22:08
PC Open Date & Time	06 AUG 2020 15:25
PC Close Date & Time	07 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

98.2 °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

07 AUG 2020 20:48

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

98.3 °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

08 AUG 2020 23:36

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 22:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

97.9 °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

11 AUG 2020 01:35

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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 AUG 2020 01:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 00:37

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

06 AUG 2020 12:17

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 14:30

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

06 AUG 2020 22:10

PC Open Date & Time

06 AUG 2020 15:25

PC Close Date & Time

07 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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 AUG 2020 20:49

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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 AUG 2020 23:36

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

09 AUG 2020 22:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 01:36

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

12 AUG 2020 01:08

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

13 AUG 2020 00:38

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 12:18
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 14:30

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

No ☒

Yes ☐

PC Time stamp	06 AUG 2020 22:11
PC Open Date & Time	06 AUG 2020 15:25
PC Close Date & Time	07 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

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 ☒

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	07 AUG 2020 20:50
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	08 AUG 2020 23:37
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

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 ☒

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	09 AUG 2020 22:27
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	11 AUG 2020 01:36
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

57 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	12 AUG 2020 01:09
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

59 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	13 AUG 2020 00:38
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Was this visit performed?	Yes ☒
	No ☐

Visit date (dd MMM yyyy)	31 AUG 2020

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

Folder OID	VISIT2

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	13:50 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 13:50
Temperature (xxx.x)	97.6 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:56
Temperature (xxx.x)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	112 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

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.

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 14:22 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 14:22

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

US3812060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	14:12 (24 HR)
Collection date and time (derived)	31 AUG 2020 14:12

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	31 AUG 2020 14:15
Nasopharyngeal Swab 2	No		

US3812060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 14:55

PC Open Date & Time

31 AUG 2020 14:42

PC Close Date & Time

31 AUG 2020 17:12

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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 98.4 °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	31 AUG 2020 21:37
PC Open Date & Time	31 AUG 2020 18:07
PC Close Date & Time	01 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

01 SEP 2020 23:29

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 22:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

98.3 °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

03 SEP 2020 23:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 00:55

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

06 SEP 2020 00:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

07 SEP 2020 00:44

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

31 AUG 2020 14:55

PC Open Date & Time

31 AUG 2020 14:42

PC Close Date & Time

31 AUG 2020 17:12

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

31 AUG 2020 21:37

PC Open Date & Time

31 AUG 2020 18:07

PC Close Date & Time

01 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

01 SEP 2020 23:29

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

02 SEP 2020 22:38

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

03 SEP 2020 23:39

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 00:56

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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 00:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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 00:45

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 14:56
PC Open Date & Time	31 AUG 2020 14:42
PC Close Date & Time	31 AUG 2020 17:12

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 21:38
PC Open Date & Time	31 AUG 2020 18:07
PC Close Date & Time	01 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	01 SEP 2020 23:31
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

97 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	02 SEP 2020 22:39
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

99 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	03 SEP 2020 23:40
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

101 of 2081

EAB) (1725)

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	05 SEP 2020 00:56
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	06 SEP 2020 00:51
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

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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US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

Yes ☐	
PC Time stamp	07 SEP 2020 00:45
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3812060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

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

US3812060

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 14:46
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3812060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Was the sample collected?	Yes ☒
	No ☐
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	15:00 (24 HR)
Collection date and time (derived)	29 SEP 2020 15:00

US3812060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:30

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 OCT 2020 18:01:48

Patient Cloud Open Date & Time

06 OCT 2020 00:01

Patient Cloud Close Date & Time

10 OCT 2020 23:59

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 13:00:53

Patient Cloud Open Date & Time

13 OCT 2020 00:01

Patient Cloud Close Date & Time

17 OCT 2020 23:59

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
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 ☒
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	23 OCT 2020 17:07:46
Patient Cloud Open Date & Time	20 OCT 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	120 of 2081

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

24 OCT 2020 23:59

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 NOV 2020 18:28:11

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

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

Date and time of submission

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3812060

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:52:46

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

US3812060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT IN CONVALESCENT
PERIOD

If Contact Not Made, please provide Comments

US3812060

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was Contact Attempted?

Yes ☐

No ☒

Date of Contact or Contact Attempt (dd MMM yyyy)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

SUBJECT EXPIRED, SEE SAE

If Contact Not Made, please provide Comments

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Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Date of Contact	26 OCT 2020
Time of Contact	12:20
Date and Time of Contact (derived)	26 OCT 2020 12:20
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☒
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☒
	No ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	21 OCT 2020

Assessment Not Done	False

O2 Saturation	ND - Not Done

O2 Saturation Units	%

Temperature	ND - Not Done

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	25 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	26 OCT 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.2 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☒
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐

Date	27 OCT 2020

Assessment Not Done	False

O2 Saturation	98 %

O2 Saturation Units	%

Temperature	97.6 F

Chills	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Cough	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Shortness of Breath	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐
	Not Done ☐

Difficulty Breathing	None ☒
	Mild ☐
	Moderate ☐
	Severe ☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☒
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Day 33	☐
	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	28 OCT 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐

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EAB) (1725)

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

	Not Done	☐
Fatigue	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

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 ☐

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Date of Visit 26 OCT 2020

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

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

Date of Test 26 OCT 2020

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

Other, specify _____

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

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 26 Mar 2021 19:31:38

Generated On: 10 Jun 2021 09:52:46

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 OCT 2020
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)	

US3812060

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 12:40
Height (xxx.x)	68.0 in
Weight (xxx.x)	174.0 lb
Temperature (xxx.x)	97.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812060

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3812060

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 20 Feb 2021 19:35:07

Generated On: 10 Jun 2021 09:52:46

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 OCT 2020

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 15:36:39

Generated On: 10 Jun 2021 09:52:46

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 _____

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 15:36:39

Generated On: 10 Jun 2021 09:52:46

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) _____

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 15:36:39

Generated On: 10 Jun 2021 09:52:46

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.

US3812060

Folder: Convalescence Visit Day 28 (1)

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

Data signed: (b) (4) 26 Apr 2021 15:36:39

Generated On: 10 Jun 2021 09:52:46

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3812060

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

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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 _____

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

Form: Unblinding

Generated On: 10 Jun 2021 09:52:46

Date of updated informed consent (<i>dd MMM yyyy</i>)		
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study		
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 (<i>dd MMM yyyy</i>)		
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		

US3812060

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Was the sample collected?	Yes ☐
	No ☐

Collection date (<i>dd MMM yyyy</i>)	_____
Collection time (<i>00:00-23:59</i>)	_____
Collection date and time (derived)	_____

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:52:46

Was the sample collected?	Yes ☐
	No ☐
Collection date (<i>dd MMM yyyy</i>)	
Collection time (<i>00:00 - 23:59</i>)	
Collection Date and Time (derived)	

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:52:46

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

AEID

Adverse event

RIGHT EYE STYE

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)

29 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)

01 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

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

US3812060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

AEID	USA-US111-2020-MRNA-1273-P30 1000017
Adverse event	MYOCARDIAL INFARCTION
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)	24 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)	24 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	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 ☐ No ☐ Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☒ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3812060

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

SITE HAS ATTEMPTED TO
CONTACT SUBJECT ON
MULTIPLE OCCASIONS
REGARDING MISSED DIARY
ENTRIES AND MISSED D119
SAFETY CALL WITHOUT
SUCCESS. SITE'S LAST
SUCCESSFUL CONTACT WITH
THE SUBJECT WAS ON 29 OCT,
2020 WHEN SUBJECT WAS
NOTIFIED OF NEGATIVE
COVID-19 SWAB. SITE CALLED
THE SUBJECT'S BROTHER, WHO
WAS LISTED AS HIS
EMERGENCY CONTACT ON 04
DEC 2020 AND PER THE
SUBJECT'S BROTHER, THE
SUBJECT WAS FOUND DEAD ON
NOV 30, 2020 BUT MAY HAVE
EXPIRED 1 WEEK PRIOR.
SUBJECT'S EXACT DATE OF
DEATH AND ETIOLOGY OF
DEATH IS UNKNOWN AT THIS
TIME. SUBJECT'S DEATH
CERTIFICATE WILL BE
REQUESTED. SAE WILL BE
UPDATED ONCE ADDITIONAL
INFORMATION IS AVAILABLE.
25 MAR 2021: DEATH
CERTIFICATE OBTAINED.
CAUSE OF DEATH IS PROBABLE
MYOCARDIAL INFARCTION.
DATE OF DEATH WAS NOTED
TO BE NOV 24, 2020

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:10:44

Generated On: 10 Jun 2021 09:52:46

AEID

Adverse event

COVID-LIKE ILLNESS

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)

16 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

21 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 13 Apr 2021 15:10:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☒
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 00:47:56

Generated On: 10 Jun 2021 09:52:46

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 2

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

If dose unit is Other, specify PACKS

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication BUPROPION HCL

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication CYMBALTA

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

Dose per administration 60

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication D3

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2005	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication ISAGENIX [UNKNOWN ACTIVE
INGREDIENTS]

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 9

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN AUG 2019	
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication FLU PREVENTION

Dose per administration 1

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

If dose unit is Other, specify DOSE

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		22 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		22 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication ZICAM- COLD REMEDY
TABLETS (ZINCUM ACETICUM /
AINCUM GLUCONISUM)

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 17 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication ZICAM- COLD REMEDY
TABLETS (ZINCUM ACETICUM /
AINCUM GLUCONISUM)

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		18 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication ZICAM- COLD REMEDY
TABLETS (ZINCUM ACETICUM /
AINCUM GLUCONISUM)

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intraocular	☐
	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	19 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication TYLENOL PM

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 16 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication TYLENOL PM

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 17 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

Name of Medication TYLENOL PM

Prophylaxis Yes ☐
No ☒

Indication COVID-LIKE ILLNESS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

237 of 2081

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 13 Apr 2021 15:10:45

Generated On: 10 Jun 2021 09:52:46

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy) 18 OCT 2020		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

Visit	Screening	☐
	Visit 1 Day 1	☐
	Visit 2 Day 29	☐
	Visit 3 Day 57	☒
	Visit 4 Day 209	☐
	Visit 5 Day 394	☐
	Visit 6 Day 759	☐

Case Report Form

Visit Date	False
Demographics	False
Enrollment	False
Inclusion/Exclusion Criteria Summary	False
Inclusion/Exclusion Criteria	False
Medical History Summary	False
Medical History	False
Vital Signs	False
Vital Signs - Dosing	False
Physical Examination	False
Central Laboratory - Nasopharyngeal Swab	False
Childbearing Potential	False
Pregnancy Test	False
Randomization	False
Exposure	False
Immunogenicity Assessment	False
Saliva Collection	False
COVID Diagnostic Test	False
Symptom Log	False
Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection	False
COVID-19 Severity Assessment	False
COVID-19 Contact	False
Risk of Exposure	False
Safety Call	True
Dosing Discontinuation	False

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Data signed: (b) (4) 20 Feb 2021 19:35:06

Generated On: 10 Jun 2021 09:52:46

End of Study / Study Discontinuation	False
All	False
Date of missed or out of window visit or assessment	27 OCT 2020
Category	
Inclusion criteria not met/Exclusion criteria met	False
Study Treatment not given	False
Missed Visit	False
Missed Assessment	False
Visit performed out of window	False
Assessment performed out of window	False
Scheduled clinical visit performed as home visit	False
Other	True
Other, specify	SUBJECT IN CONVALESCENT PERIOD, SAFETY CALL DAY 85 NOT PERFORMED
Description of Relationship to COVID-19	
Clinical site closed	False
Travel restrictions	False
Quarantine due to COVID-19	False
Possible exposure to COVID-19	False
Exposure to COVID-19	False
Presumption / confirmed COVID-19	True
Symptoms of COVID-19	False
Sponsor hold due to COVID-19	False
Participant decision	False

US3812060

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:52:46

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3812060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Data signed: (b) (4) 23 Apr 2021 15:18:29

Generated On: 10 Jun 2021 09:52:46

Date of study discontinuation/completion (dd MMM yyyy) 30 NOV 2020

Reason for discontinuation

AE (specify)	☐
SAE (specify)	☐
Complete	☐
Death	☒
Lost To Follow-up	☐
Physician decision (specify)	☐
Pregnancy	☐
Protocol deviation (specify)	☐
Study Terminated By Sponsor	☐
Withdrawal of consent by participant (specify)	☐
Other	☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event	☒
Unknown	☐
Other	☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy) 30 NOV 2020

Was autopsy performed?

Yes	☐
No	☐
Unknown	☒

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Data signed: (b) (4) 12 Apr 2021 15:03:03

Generated On: 10 Jun 2021 09:52:46

SAEID	USA-US111-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Data signed: (b) (4) 12 Apr 2021 15:03:03

Generated On: 10 Jun 2021 09:52:46

SAEID	USA-US111-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	05/DEC/2020 17:58
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

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Data signed: (b) (4) 12 Apr 2021 15:03:03

Generated On: 10 Jun 2021 09:52:46

SAEID	USA-US111-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	28/DEC/2020 18:17
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

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Data signed: (b) (4) 12 Apr 2021 15:03:03

Generated On: 10 Jun 2021 09:52:46

SAEID	USA-US111-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	26/MAR/2021 14:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Data signed: (b) (4) 12 Apr 2021 15:03:03

Generated On: 10 Jun 2021 09:52:46

SAEID	USA-US111-2020-MRNA-1273-P301000017
Serious	Yes ☒ No ☐
Death	Yes ☒ No ☐
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☐ No ☒
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	09/APR/2021 10:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3812060 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812060

Form: Participant Creation

Generated On: 10 Jun 2021 09:52:46

[Participant ID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'US3812060'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:14:42

US3812060

Form: Participant Creation

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:22

US3812060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:14:43

US3812060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:22

US3812060

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'SCRN'	System	06 Aug 2020 16:51:22

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered (b) (6) 1958'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:14:44

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '62'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'YEARS'	System	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '62'	System	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Male (M)'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '1'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:52:46

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:15:34

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

Date of Informed Consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:54:07
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 16:51:39
	(b) (4)	

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Aug 2020'	System	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2020'	System	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Amendment 1 (1)'	Heather Cherniawski	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:39

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Heather Cherniawski	06 Aug 2020 16:51:39

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:14:43

US3812060

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:52:46

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 16:51:45

US3812060

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:51:45

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Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:52:46

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:15:53

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Inguinal hernia repair, LLT: Inguinal hernia repair - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 14:18:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 14:18:46
Data point term sent to Coder	System	27 Oct 2020 20:46:37
Coding entries removed.	Lyly Dang (b) (4)	27 Oct 2020 20:46:28
User entered 'LEFT SIDE inguinal HERNIA OPERATION' reason for change: Data Entry Error	Lyly Dang (b) (4)	27 Oct 2020 20:46:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Hernia repair, LLT: Hernia repair - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 12:01:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	28 Aug 2020 12:01:38
Data point term sent to Coder	System	06 Aug 2020 22:16:46
User entered 'LEFT SIDE HERNIA OPERATION'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

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Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 1966'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 1966'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 1966'	System	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1966'	System	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 1966'	System	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1966'	System	06 Aug 2020 22:16:18

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Inguinal hernias, PT: Inguinal hernia, LLT: Left inguinal hernia - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 20:48:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Oct 2020 20:48:39
Data point term sent to Coder	System	27 Oct 2020 20:47:38
Coding entries removed.	Lyly Dang (b) (4)	27 Oct 2020 20:46:40
User entered 'LEFT SIDE inguinal HERNIA' reason for change: Data Entry Error	Lyly Dang (b) (4)	27 Oct 2020 20:46:40
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:34:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	18 Aug 2020 23:34:03
Data point term sent to Coder	System	06 Aug 2020 22:16:46
User entered 'LEFT SIDE HERNIA'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered (b) (6) 1958'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 1966'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered (b) (6) 1958'	System	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1958'	System	06 Aug 2020 22:16:42

US3812060

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 1966'	System	06 Aug 2020 22:16:42

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1966'	System	06 Aug 2020 22:16:42

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Investigations, HLGt: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
Data point term sent to Coder	System	06 Aug 2020 22:17:48
User entered 'HIGH CHOLESTEROL'	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 1998'	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 1998'	System	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1998'	System	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:16:57

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:16:57

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
Data point term sent to Coder	System	06 Aug 2020 22:17:48
User entered 'DEPRESSION'	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 2000'	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:17:12

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 2000'	System	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2000'	System	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:17:12

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Aug 2020 22:17:58
Data point term sent to Coder	System	06 Aug 2020 22:17:49
User entered 'ANXIETY'	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 1967'	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

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Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 1967'	System	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1967'	System	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:17:30

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Tinnitus - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:50:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:50:14
Data point term sent to Coder	System	11 Aug 2020 22:49:22
User entered 'Tinnitis'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'UN UNK 2019'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 2019'	System	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2019'	System	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:49:04

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Presbycusis, LLT: Presbycusis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:45:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 12:45:13
Data point term sent to Coder	System	11 Aug 2020 22:50:24
User entered 'Presbycusis Both Side'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'un UNK 2019'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 2019'	System	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2019'	System	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:49:42

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Gastrointestinal neoplasms benign, HLT: Lower gastrointestinal neoplasms benign, PT: Colon adenoma, LLT: Colonic tubular adenoma - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 10:16:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 10:16:22
Data point term sent to Coder	System	11 Aug 2020 22:50:24
User entered 'Tubular Adenoma of Colon'	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'un UNK 2019'	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Megan Dandurand (b) (4)	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'Jan 2019'	System	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2019'	System	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Aug 2020 22:50:16

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:54:29
User entered '6 Aug 2020'	(b) (4)	
	Karen Knapp (b) (4)	06 Aug 2020 22:18:34
	(b) (4)	

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '09:59'	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 09:59'	System	11 Nov 2020 15:54:29
User entered '6 Aug 2020 09:59'	System	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '68.0' in	Karen Knapp (b) (4)	06 Aug 2020 22:18:34
DataPoint set to visible.	System	06 Aug 2020 16:51:45

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '174' lb	Karen Knapp (b) (4)	06 Aug 2020 22:18:34
DataPoint set to visible.	System	06 Aug 2020 16:51:45

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: User entered '26.51193'	System	16 Sep 2020 23:45:38
User entered '26.5'	System	06 Aug 2020 22:18:34
DataPoint set to visible.	System	06 Aug 2020 16:51:45

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'kg/m2'	System	06 Aug 2020 22:18:34
DataPoint set to visible.	System	06 Aug 2020 16:51:45

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 11:18:28
Query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:55:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:55:48
User opened query 'Per CDM: Per CCG, "ND" should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly. NOTE: Route is not required (blank).' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:02:35
User entered '97.4' F	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 16:55:48
User entered 'Oral (Oral)'	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 16:55:48
User entered '56'	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:55:48
User entered '14'	Angie Kean (b) (4)	06 Aug 2020 22:18:34
	Karen Knapp (b) (4)	
	(b) (4)	

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	23 Nov 2020 16:55:48
User entered '118'	Angie Kean (b) (4)	06 Aug 2020 22:18:34
	Karen Knapp (b) (4)	
	(b) (4)	

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 16:55:48
User entered '86'	Karen Knapp (b) (4)	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:18:34

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:20:50

US3812060

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:18:50

US3812060

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4)	11 Nov 2020 15:54:38
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:59:13
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		31 Aug 2020 19:53:08
User entered '6 Aug 2020'	Karen Knapp (b) (4)	06 Aug 2020 22:18:50

US3812060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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[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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
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	06 Aug 2020 22:20:29
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	06 Aug 2020 22:20:29
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	06 Aug 2020 22:20:13
	Karen Knapp (b) (4)	06 Aug 2020 22:20:13
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

US3812060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

[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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '1'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

US3812060

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:52:46

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'ROUTINE GYM ACTIVITY 5X WEEK AND INTERACTS WITH 5 OR MORE PEOPLE'	Karen Knapp (b) (4)	06 Aug 2020 22:20:13

US3812060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:52:02

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:54:51
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 16:52:02
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:52:02

US3812060

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'VISIT1'	System	06 Aug 2020 16:52:02

US3812060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:15:16

US3812060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:33:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:33:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Aug 2020 16:15:16
User entered '101558' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:15:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	06 Aug 2020 16:15:16

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Sep 2020 09:15:18
Query 'PER CDM: Please complete this section of the form.' answered with 'updated per query' (Site from DM).	Anya Penly (b) (4) (b) (4)	04 Sep 2020 17:41:19
User entered 'No (N)'	Anya Penly (b) (4) (b) (4)	04 Sep 2020 17:40:39
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 09:05:44

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Any Penly (b) (4)	04 Sep 2020 17:40:39

US3812060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Any Penly (b) (4)	04 Sep 2020 17:40:39

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Any Penly (b) (4)	04 Sep 2020 17:40:39

US3812060

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:52:46

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Any Penly (b) (4)	04 Sep 2020 17:40:39

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 11:22:50
Query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:40
User opened query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:42:19
User entered '68' in	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 16:52:40
User entered '174' lb	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 11:22:50
Query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:40
User opened query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:42:19
User entered '68' in	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Nov 2020 16:52:40
User entered '174' lb	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Pre-Dose (PREDOSE)'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:55:10
User entered '6 Aug 2020'	(b) (4)	
	Karen Knapp (b) (4)	06 Aug 2020 22:22:56
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '09:59'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 09:59'	System	11 Nov 2020 15:55:10
User entered '6 Aug 2020 09:59'	System	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '97.4' F	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Oral (Oral)'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '56'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '118'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '86'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Nov 2020 11:22:50
Query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	23 Nov 2020 16:52:40
User opened query 'Per CDM: Per CCGs v2 pgs. 17-18, since Screening and Visit 1 were done on the same day, please remove data from HEIGHT and WEIGHT and indicate as "ND-Not Done". Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 15:42:19
User entered '68' in	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:52:46

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered missing code ND - Not Done; reason for change Data Entry Error	Angie Kean (b) (4)	23 Nov 2020 16:52:40
User entered '174' lb	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Post-Dose (POSTDOSE)'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:55:21
User entered '6 Aug 2020'	(b) (4)	
	Karen Knapp (b) (4)	06 Aug 2020 22:22:56
	(b) (4)	

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Aug 2020 16:44:01
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'DM error' (Site from System).	Anya Penly (b) (4) (b) (4)	08 Aug 2020 13:56:38
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		06 Aug 2020 22:22:56
User entered '12:12'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 12:12'	System	11 Nov 2020 15:55:21
User entered '6 Aug 2020 12:12'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '97.4' F	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Oral (Oral)'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '60'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '16'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '120'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

US3812060

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '76'	Karen Knapp (b) (4)	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	06 Aug 2020 22:22:56

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:04:18
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:23:49

US3812060

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	16 Sep 2020 23:04:18
User entered '6 Aug 2020'	Karen Knapp (b) (4)	06 Aug 2020 22:23:49

US3812060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Heather Cherniawski	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Heather Cherniawski (b) (4)	06 Aug 2020 16:57:29

US3812060

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'MRNA-1273 OR PLACEBO'	System	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:55:40
User entered '6 Aug 2020'	(b) (4)	
	Heather Cherniawski	06 Aug 2020 16:57:29
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '11:40'	Heather Cherniawski (b) (4)	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 11:40'	System	11 Nov 2020 15:55:40
User entered '6 Aug 2020 11:40'	System	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Right Arm (RIGHT ARM)'	Heather Cherniawski	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'ONCE'	System	06 Aug 2020 16:57:29

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'INTRAMUSCULAR'	System	06 Aug 2020 16:57:29

US3812060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:25:03

US3812060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:55:49
User entered '6 Aug 2020'	(b) (4)	
	Karen Knapp (b) (4)	06 Aug 2020 22:25:03
	(b) (4)	

US3812060

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Aug 2020 14:30:03
User entered '11:34' reason for change: Data Entry Error	System	08 Aug 2020 14:30:03
User opened query 'Data is required. Please provide.' (Site from System).	Anya Penly (b) (4)	08 Aug 2020 14:30:03
User entered empty.	(b) (4)	06 Aug 2020 22:25:03
	Karen Knapp (b) (4)	06 Aug 2020 22:25:03
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 11:34'	System	11 Nov 2020 15:55:49
User entered '6 Aug 2020 11:34'	System	08 Aug 2020 14:30:03
User entered empty.	System	06 Aug 2020 22:25:03

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '06 Aug 2020' reason for change: Per Query Resolution	(b) (4)	
	Karen Knapp (b) (4)	11 Nov 2020 15:55:57
User entered '6 Aug 2020'	(b) (4)	
	Karen Knapp (b) (4)	06 Aug 2020 22:25:25
	(b) (4)	

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '11:37'	Karen Knapp (b) (4)	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '06 Aug 2020 11:37'	System	11 Nov 2020 15:55:57
User entered '6 Aug 2020 11:37'	System	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:25:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	06 Aug 2020 22:25:25

US3812060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:25:32

US3812060

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:25:32

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:16:18', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0cf05450-1c2f-498d-a326-7ac8dd81d38d'	System	06 Aug 2020 17:17:01
User entered 'Yes (Y)'	System	06 Aug 2020 17:17:01

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:16:26', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0cf05450-1c2f-498d-a326-7ac8dd81d38d'	System	06 Aug 2020 17:17:01
User entered '97.4'	System	06 Aug 2020 17:17:01

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:16:34', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0cf05450-1c2f-498d-a326-7ac8dd81d38d'	System	06 Aug 2020 17:17:01
User entered 'No (N)'	System	06 Aug 2020 17:17:01

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:16:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0cf05450-1c2f-498d-a326-7ac8dd81d38d'	System	06 Aug 2020 17:17:01
User entered '06 Aug 2020 12:16'	System	06 Aug 2020 17:17:01

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:08:40', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2de41d87-5c14-423b-ae50-35b445869584'	System	07 Aug 2020 03:08:52
User entered 'Yes (Y)'	System	07 Aug 2020 03:08:52

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:08:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2de41d87-5c14-423b-ae50-35b445869584' User entered '98.0'	System	07 Aug 2020 03:08:52
	System	07 Aug 2020 03:08:52

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:08:30', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2de41d87-5c14-423b-ae50-35b445869584'	System	07 Aug 2020 03:08:52
User entered 'No (N)'	System	07 Aug 2020 03:08:52

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:08:49', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2de41d87-5c14-423b-ae50-35b445869584'	System	07 Aug 2020 03:08:52
User entered '06 Aug 2020 22:08'	System	07 Aug 2020 03:08:52

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 15:25'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 2'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:48:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4ac9a2fa-34d2-4b30-ac31-6f991f6a92da'	System	08 Aug 2020 01:48:43
User entered 'Yes (Y)'	System	08 Aug 2020 01:48:43

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:48:28', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4ac9a2fa-34d2-4b30-ac31-6f991f6a92da'	System	08 Aug 2020 01:48:43
User entered '98.2'	System	08 Aug 2020 01:48:43

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:48:34', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4ac9a2fa-34d2-4b30-ac31-6f991f6a92da'	System	08 Aug 2020 01:48:43
User entered 'No (N)'	System	08 Aug 2020 01:48:43

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:48:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4ac9a2fa-34d2-4b30-ac31-6f991f6a92da'	System	08 Aug 2020 01:48:43
User entered '07 Aug 2020 20:48'	System	08 Aug 2020 01:48:43

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 3'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:35:44', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '917f9eef-8147-4a97-8c28-0a5eb83bbd5c'	System	09 Aug 2020 04:36:02
User entered 'Yes (Y)'	System	09 Aug 2020 04:36:02

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:35:50', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '917f9eef-8147-4a97-8c28-0a5eb83bbd5c'	System	09 Aug 2020 04:36:02
User entered '98.3'	System	09 Aug 2020 04:36:02

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:35:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '917f9eef-8147-4a97-8c28-0a5eb83bbd5c'	System	09 Aug 2020 04:36:02
User entered 'No (N)'	System	09 Aug 2020 04:36:02

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:01', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '917f9eef-8147-4a97-8c28-0a5eb83bbd5c'	System	09 Aug 2020 04:36:02
User entered '08 Aug 2020 23:36'	System	09 Aug 2020 04:36:02

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 4'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:25:50', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'cb677f6c-7150-40d8-ae20-fa689c6378cf'	System	10 Aug 2020 03:26:10
User entered 'Yes (Y)'	System	10 Aug 2020 03:26:10

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:25:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'cb677f6c-7150-40d8-ae20-fa689c6378cf'	System	10 Aug 2020 03:26:10
User entered '98.5'	System	10 Aug 2020 03:26:10

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'cb677f6c-7150-40d8-ae20-fa689c6378cf'	System	10 Aug 2020 03:26:10
User entered 'No (N)'	System	10 Aug 2020 03:26:10

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'cb677f6c-7150-40d8-ae20-fa689c6378cf'	System	10 Aug 2020 03:26:10
User entered '09 Aug 2020 22:26'	System	10 Aug 2020 03:26:10

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 5'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:34:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '420ef648-0072-4307-ae08-7e18c42e6d50'	System	11 Aug 2020 06:35:30
User entered 'Yes (Y)'	System	11 Aug 2020 06:35:30

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '420ef648-0072-4307-ae08-7e18c42e6d50'	System	11 Aug 2020 06:35:30
User entered '97.9'	System	11 Aug 2020 06:35:30

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '420ef648-0072-4307-ae08-7e18c42e6d50'	System	11 Aug 2020 06:35:30
User entered 'No (N)'	System	11 Aug 2020 06:35:30

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:27', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '420ef648-0072-4307-ae08-7e18c42e6d50'	System	11 Aug 2020 06:35:30
User entered '11 Aug 2020 01:35'	System	11 Aug 2020 06:35:30

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 6'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:04:52', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2f1dfb76-015f-4d1f-9837-e396ef0c669e'	System	12 Aug 2020 06:08:27
User entered 'Yes (Y)'	System	12 Aug 2020 06:08:27

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2f1dfb76-015f-4d1f-9837-e396ef0c669e' User entered '96.0'	System	12 Aug 2020 06:08:27
	System	12 Aug 2020 06:08:27

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2f1dfb76-015f-4d1f-9837-e396ef0c669e'	System	12 Aug 2020 06:08:27
User entered 'No (N)'	System	12 Aug 2020 06:08:27

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:23', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2f1dfb76-015f-4d1f-9837-e396ef0c669e'	System	12 Aug 2020 06:08:27
User entered '12 Aug 2020 01:08'	System	12 Aug 2020 06:08:27

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 7'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '75749211-795d-4e36-bfc9-9497856832a9'	System	13 Aug 2020 05:37:50
User entered 'Yes (Y)'	System	13 Aug 2020 05:37:50

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '75749211-795d-4e36-bfc9-9497856832a9' User entered '96.8'	System	13 Aug 2020 05:37:50
	System	13 Aug 2020 05:37:50

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:42', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '75749211-795d-4e36-bfc9-9497856832a9'	System	13 Aug 2020 05:37:50
User entered 'No (N)'	System	13 Aug 2020 05:37:50

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '75749211-795d-4e36-bfc9-9497856832a9'	System	13 Aug 2020 05:37:50
User entered '13 Aug 2020 00:37'	System	13 Aug 2020 05:37:50

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:17:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0ce3d477-e56e-4deb-83b9-33cbe51baecf'	System	06 Aug 2020 17:18:02
User entered 'None (1)'	System	06 Aug 2020 17:18:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:17:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0ce3d477-e56e-4deb-83b9-33cbe51baecf'	System	06 Aug 2020 17:18:02
User entered 'No (N)'	System	06 Aug 2020 17:18:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:17:34', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0ce3d477-e56e-4deb-83b9-33cbe51baecf'	System	06 Aug 2020 17:18:02
User entered 'No (N)'	System	06 Aug 2020 17:18:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:17:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0ce3d477-e56e-4deb-83b9-33cbe51baecf'	System	06 Aug 2020 17:18:02
User entered 'None (1)'	System	06 Aug 2020 17:18:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:17:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '0ce3d477-e56e-4deb-83b9-33cbe51baecf'	System	06 Aug 2020 17:18:02
User entered '06 Aug 2020 12:17'	System	06 Aug 2020 17:18:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:09:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e91c0739-58a6-455c-b1db-f478a509efc3'	System	07 Aug 2020 03:10:32
User entered 'None (1)'	System	07 Aug 2020 03:10:32

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:09:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e91c0739-58a6-455c-b1db-f478a509efc3'	System	07 Aug 2020 03:10:32
User entered 'No (N)'	System	07 Aug 2020 03:10:32

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:09:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e91c0739-58a6-455c-b1db-f478a509efc3'	System	07 Aug 2020 03:10:32
User entered 'No (N)'	System	07 Aug 2020 03:10:32

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e91c0739-58a6-455c-b1db-f478a509efc3'	System	07 Aug 2020 03:10:32
User entered 'None (1)'	System	07 Aug 2020 03:10:32

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:30', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e91c0739-58a6-455c-b1db-f478a509efc3'	System	07 Aug 2020 03:10:32
User entered '06 Aug 2020 22:10'	System	07 Aug 2020 03:10:32

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 15:25'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 2'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:48:54', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3158b49c-5a60-4067-a401-bd1c306803c3'	System	08 Aug 2020 01:49:49
User entered 'None (1)'	System	08 Aug 2020 01:49:49

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3158b49c-5a60-4067-a401-bd1c306803c3'	System	08 Aug 2020 01:49:49
User entered 'No (N)'	System	08 Aug 2020 01:49:49

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3158b49c-5a60-4067-a401-bd1c306803c3'	System	08 Aug 2020 01:49:49
User entered 'No (N)'	System	08 Aug 2020 01:49:49

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3158b49c-5a60-4067-a401-bd1c306803c3'	System	08 Aug 2020 01:49:49
User entered 'None (1)'	System	08 Aug 2020 01:49:49

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:47', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3158b49c-5a60-4067-a401-bd1c306803c3'	System	08 Aug 2020 01:49:49
User entered '07 Aug 2020 20:49'	System	08 Aug 2020 01:49:49

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 3'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:06', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b58a577-cef4-460a-ae52-1ec6094c33ef'	System	09 Aug 2020 04:36:57
User entered 'None (1)'	System	09 Aug 2020 04:36:57

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b58a577-cef4-460a-ae52-1ec6094c33ef'	System	09 Aug 2020 04:36:57
User entered 'No (N)'	System	09 Aug 2020 04:36:57

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:14', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b58a577-cef4-460a-ae52-1ec6094c33ef'	System	09 Aug 2020 04:36:57
User entered 'No (N)'	System	09 Aug 2020 04:36:57

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:52', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b58a577-cef4-460a-ae52-1ec6094c33ef'	System	09 Aug 2020 04:36:57
User entered 'None (1)'	System	09 Aug 2020 04:36:57

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:36:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b58a577-cef4-460a-ae52-1ec6094c33ef'	System	09 Aug 2020 04:36:57
User entered '08 Aug 2020 23:36'	System	09 Aug 2020 04:36:57

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 4'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:33', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41480b49-5dd7-4d00-9eaf-a1b70287cb9f'	System	10 Aug 2020 03:27:02
User entered 'None (1)'	System	10 Aug 2020 03:27:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:37', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41480b49-5dd7-4d00-9eaf-a1b70287cb9f'	System	10 Aug 2020 03:27:02
User entered 'No (N)'	System	10 Aug 2020 03:27:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41480b49-5dd7-4d00-9eaf-a1b70287cb9f'	System	10 Aug 2020 03:27:02
User entered 'No (N)'	System	10 Aug 2020 03:27:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:55', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41480b49-5dd7-4d00-9eaf-a1b70287cb9f'	System	10 Aug 2020 03:27:02
User entered 'None (1)'	System	10 Aug 2020 03:27:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:26:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41480b49-5dd7-4d00-9eaf-a1b70287cb9f'	System	10 Aug 2020 03:27:02
User entered '09 Aug 2020 22:26'	System	10 Aug 2020 03:27:02

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 5'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b1601b6d-34d7-4414-989d-c15da58067ea'	System	11 Aug 2020 06:36:04
User entered 'None (1)'	System	11 Aug 2020 06:36:04

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:36', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b1601b6d-34d7-4414-989d-c15da58067ea'	System	11 Aug 2020 06:36:04
User entered 'No (N)'	System	11 Aug 2020 06:36:04

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b1601b6d-34d7-4414-989d-c15da58067ea'	System	11 Aug 2020 06:36:04
User entered 'No (N)'	System	11 Aug 2020 06:36:04

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:35:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b1601b6d-34d7-4414-989d-c15da58067ea'	System	11 Aug 2020 06:36:04
User entered 'None (1)'	System	11 Aug 2020 06:36:04

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b1601b6d-34d7-4414-989d-c15da58067ea'	System	11 Aug 2020 06:36:04
User entered '11 Aug 2020 01:36'	System	11 Aug 2020 06:36:04

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 6'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:27', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '094da34b-c95e-47b4-a9ae-f91ec39fd603'	System	12 Aug 2020 06:08:43
User entered 'None (1)'	System	12 Aug 2020 06:08:43

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:31', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '094da34b-c95e-47b4-a9ae-f91ec39fd603'	System	12 Aug 2020 06:08:43
User entered 'No (N)'	System	12 Aug 2020 06:08:43

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:35', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '094da34b-c95e-47b4-a9ae-f91ec39fd603'	System	12 Aug 2020 06:08:43
User entered 'No (N)'	System	12 Aug 2020 06:08:43

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '094da34b-c95e-47b4-a9ae-f91ec39fd603'	System	12 Aug 2020 06:08:43
User entered 'None (1)'	System	12 Aug 2020 06:08:43

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '094da34b-c95e-47b4-a9ae-f91ec39fd603'	System	12 Aug 2020 06:08:43
User entered '12 Aug 2020 01:08'	System	12 Aug 2020 06:08:43

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 7'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41f6dca3-9bee-4f77-befa-e1570e9caf5e'	System	13 Aug 2020 05:38:07
User entered 'None (1)'	System	13 Aug 2020 05:38:07

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:54', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41f6dca3-9bee-4f77-befa-e1570e9caf5e'	System	13 Aug 2020 05:38:07
User entered 'No (N)'	System	13 Aug 2020 05:38:07

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:37:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41f6dca3-9bee-4f77-befa-e1570e9caf5e'	System	13 Aug 2020 05:38:07
User entered 'No (N)'	System	13 Aug 2020 05:38:07

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41f6dca3-9bee-4f77-befa-e1570e9caf5e'	System	13 Aug 2020 05:38:07
User entered 'None (1)'	System	13 Aug 2020 05:38:07

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '41f6dca3-9bee-4f77-befa-e1570e9caf5e'	System	13 Aug 2020 05:38:07
User entered '13 Aug 2020 00:38'	System	13 Aug 2020 05:38:07

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'None (0)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:35', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered 'No (N)'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T12:18:39', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'ce048b1a-6994-44f0-af26-f745158ebf66'	System	06 Aug 2020 17:18:44
User entered '06 Aug 2020 12:18'	System	06 Aug 2020 17:18:44

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 14:30'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:35', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:42', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:49', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'None (0)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:10:58', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered 'No (N)'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-06T22:11:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '778831ee-2894-4c9a-b4b4-e445f2e9e630'	System	07 Aug 2020 03:11:09
User entered '06 Aug 2020 22:11'	System	07 Aug 2020 03:11:09

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Aug 2020 15:25'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 2'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:55', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:49:58', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:01', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:04', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'None (0)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered 'No (N)'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-07T20:50:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd1d8776e-53b7-4e31-8d5c-750562491f41'	System	08 Aug 2020 01:50:23
User entered '07 Aug 2020 20:50'	System	08 Aug 2020 01:50:23

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 3'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:22', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'None (0)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:29', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered 'No (N)'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-08T23:37:34', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f022e018-45d5-4d42-bead-98415c181e05'	System	09 Aug 2020 04:37:36
User entered '08 Aug 2020 23:37'	System	09 Aug 2020 04:37:36

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '08 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 4'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:35', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'None (0)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered 'No (N)'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-09T22:27:40', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '2b2308b0-96dd-47f3-83b3-b5e6cfee6578'	System	10 Aug 2020 03:27:43
User entered '09 Aug 2020 22:27'	System	10 Aug 2020 03:27:43

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '09 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 5'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:06', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:11', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:14', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:18', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'None (0)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered 'No (N)'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-11T01:36:30', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'bb81c67f-ffd0-4286-8d0f-bbcaf01269e0'	System	11 Aug 2020 06:36:31
User entered '11 Aug 2020 01:36'	System	11 Aug 2020 06:36:31

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '10 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 6'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:50', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:08:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:09:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:09:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:09:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'None (0)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:09:12', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered 'No (N)'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-12T01:09:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '6bc9b3b2-d95b-4172-8c2e-bc8423eadd09'	System	12 Aug 2020 06:09:18
User entered '12 Aug 2020 01:09'	System	12 Aug 2020 06:09:18

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '11 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 7'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:09', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:11', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:17', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'None (0)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:26', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered 'No (N)'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-13T00:38:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '4a97948e-1f19-4a7b-990c-c5129f5653b0'	System	13 Aug 2020 05:38:33
User entered '13 Aug 2020 00:38'	System	13 Aug 2020 05:38:33

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '12 Aug 2020 12:00'	System	06 Aug 2020 16:57:29

US3812060

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '13 Aug 2020 11:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Aug 2020 20:11:16

US3812060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '13 Aug 2020'	Breanna Galibert (b) (4)	13 Aug 2020 20:11:16

US3812060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	13 Aug 2020 20:11:16

US3812060

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	13 Aug 2020 20:11:16

US3812060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:36:38

US3812060

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	25 Aug 2020 22:36:38

US3812060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Aug 2020 22:36:46

US3812060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '21 Aug 2020'	Breanna Galibert (b) (4)	25 Aug 2020 22:36:46

US3812060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	25 Aug 2020 22:36:46

US3812060

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	25 Aug 2020 22:36:46

US3812060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Aug 2020 19:52:53

US3812060

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	31 Aug 2020 19:52:53

US3812060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Sep 2020 14:41:03

US3812060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '28 Aug 2020'	(b) (4), (b) (6)	03 Sep 2020 14:41:03

US3812060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Sep 2020 14:41:03

US3812060

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 14:41:03

US3812060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Aug 2020 19:52:58

US3812060

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	31 Aug 2020 19:52:58

US3812060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Aug 2020 19:53:08

US3812060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'within -3 day window' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 06:37:06
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	Anya Penly (b) (4)	04 Sep 2020 17:42:19
User entered '31 Aug 2020'	System	31 Aug 2020 19:53:08
	Breanna Galibert (b) (4)	31 Aug 2020 19:53:08
	(b) (4)	

US3812060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	31 Aug 2020 19:53:08

US3812060

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'VISIT2'	System	31 Aug 2020 19:53:08

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '13:50'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '31 Aug 2020 13:50'	System	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '65'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '122'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '85'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	15 Sep 2020 01:51:01

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14:56'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '31 Aug 2020 14:56'	System	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '97.1' F	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '66'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '12'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '112'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '72'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	15 Sep 2020 01:52:22

US3812060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:53:00

US3812060

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:53:00

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '31 Aug 2020'	Breanna Galibert (b) (4)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14:22'	Breanna Galibert (b) (4)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '31 Aug 2020 14:22'	System	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Right Arm (RIGHT ARM)'	Breanna Galibert (b) (4)	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'ONCE'	System	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:52:46

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 19:53:21

US3812060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:54:29

US3812060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '31 Aug 2020'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:54:29

US3812060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14:12'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:54:29

US3812060

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '31 Aug 2020 14:12'	System	15 Sep 2020 01:54:29

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	06 Oct 2020 22:25:09
User entered '31 Aug 2020' reason for change: Data Entry Error	System	06 Oct 2020 22:25:09
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	06 Oct 2020 22:25:09
User entered empty.	System	15 Sep 2020 01:54:06
	(b) (4), (b) (6)	15 Sep 2020 01:53:59

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Sep 2020 01:53:59

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:53:59

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14:15'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:53:59

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '31 Aug 2020 14:15'	System	06 Oct 2020 22:25:09
User entered empty.	System	15 Sep 2020 01:53:59

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Sep 2020 01:54:06

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:54:06

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Sep 2020 01:54:06

US3812060

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	15 Sep 2020 01:54:06

US3812060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 13:56:08

US3812060

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	09 Sep 2020 13:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:54:26', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7860a277-7f1a-4174-84e8-cac28d34c8f4'	System	31 Aug 2020 19:55:04
User entered 'Yes (Y)'	System	31 Aug 2020 19:55:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:54:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7860a277-7f1a-4174-84e8-cac28d34c8f4'	System	31 Aug 2020 19:55:04
User entered '97.1'	System	31 Aug 2020 19:55:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:54:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7860a277-7f1a-4174-84e8-cac28d34c8f4'	System	31 Aug 2020 19:55:04
User entered 'No (N)'	System	31 Aug 2020 19:55:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:01', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7860a277-7f1a-4174-84e8-cac28d34c8f4'	System	31 Aug 2020 19:55:04
User entered '31 Aug 2020 14:55'	System	31 Aug 2020 19:55:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 14:42'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 17:12'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:36:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '56bd34d7-85f1-4076-be41-b9d3ce84fddf'	System	01 Sep 2020 02:37:11
User entered 'Yes (Y)'	System	01 Sep 2020 02:37:11

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:36:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '56bd34d7-85f1-4076-be41-b9d3ce84fddf' User entered '98.4'	System	01 Sep 2020 02:37:11
	System	01 Sep 2020 02:37:11

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:01', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '56bd34d7-85f1-4076-be41-b9d3ce84fddf'	System	01 Sep 2020 02:37:11
User entered 'No (N)'	System	01 Sep 2020 02:37:11

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:06', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '56bd34d7-85f1-4076-be41-b9d3ce84fddf'	System	01 Sep 2020 02:37:11
User entered '31 Aug 2020 21:37'	System	01 Sep 2020 02:37:11

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 18:07'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 2'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:28:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c84720d2-be76-4ef6-8cf0-7547c0ad8c30'	System	02 Sep 2020 04:29:04
User entered 'Yes (Y)'	System	02 Sep 2020 04:29:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:28:52', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c84720d2-be76-4ef6-8cf0-7547c0ad8c30'	System	02 Sep 2020 04:29:04
User entered '98.3'	System	02 Sep 2020 04:29:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:28:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c84720d2-be76-4ef6-8cf0-7547c0ad8c30'	System	02 Sep 2020 04:29:04
User entered 'No (N)'	System	02 Sep 2020 04:29:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c84720d2-be76-4ef6-8cf0-7547c0ad8c30'	System	02 Sep 2020 04:29:04
User entered '01 Sep 2020 23:29'	System	02 Sep 2020 04:29:04

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 3'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'a705b5e7-d63e-4457-a1a9-e736cc638d11'	System	03 Sep 2020 03:38:36
User entered 'Yes (Y)'	System	03 Sep 2020 03:38:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:22', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'a705b5e7-d63e-4457-a1a9-e736cc638d11'	System	03 Sep 2020 03:38:36
User entered '97.2'	System	03 Sep 2020 03:38:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:27', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'a705b5e7-d63e-4457-a1a9-e736cc638d11'	System	03 Sep 2020 03:38:36
User entered 'No (N)'	System	03 Sep 2020 03:38:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'a705b5e7-d63e-4457-a1a9-e736cc638d11'	System	03 Sep 2020 03:38:36
User entered '02 Sep 2020 22:38'	System	03 Sep 2020 03:38:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 4'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:38:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3b3e3cec-b694-4b93-b0bd-e71f91ddbde3'	System	04 Sep 2020 04:39:10
User entered 'Yes (Y)'	System	04 Sep 2020 04:39:10

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:38:55', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3b3e3cec-b694-4b93-b0bd-e71f91ddbde3'	System	04 Sep 2020 04:39:10
User entered '98.3'	System	04 Sep 2020 04:39:10

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3b3e3cec-b694-4b93-b0bd-e71f91ddbde3'	System	04 Sep 2020 04:39:10
User entered 'No (N)'	System	04 Sep 2020 04:39:10

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '3b3e3cec-b694-4b93-b0bd-e71f91ddbde3'	System	04 Sep 2020 04:39:10
User entered '03 Sep 2020 23:39'	System	04 Sep 2020 04:39:10

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 5'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:23', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e119e47e-7db1-41a3-9628-52d11c7e75dd'	System	05 Sep 2020 05:55:47
User entered 'Yes (Y)'	System	05 Sep 2020 05:55:47

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:40', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e119e47e-7db1-41a3-9628-52d11c7e75dd'	System	05 Sep 2020 05:55:47
User entered '98.3'	System	05 Sep 2020 05:55:47

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e119e47e-7db1-41a3-9628-52d11c7e75dd'	System	05 Sep 2020 05:55:47
User entered 'No (N)'	System	05 Sep 2020 05:55:47

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:45', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e119e47e-7db1-41a3-9628-52d11c7e75dd'	System	05 Sep 2020 05:55:47
User entered '05 Sep 2020 00:55'	System	05 Sep 2020 05:55:47

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 6'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:50:58', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd84f69c0-e149-4415-97b5-3e68b6224217'	System	06 Sep 2020 05:51:16
User entered 'Yes (Y)'	System	06 Sep 2020 05:51:16

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:04', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd84f69c0-e149-4415-97b5-3e68b6224217'	System	06 Sep 2020 05:51:16
User entered '97.9'	System	06 Sep 2020 05:51:16

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:08', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd84f69c0-e149-4415-97b5-3e68b6224217'	System	06 Sep 2020 05:51:16
User entered 'No (N)'	System	06 Sep 2020 05:51:16

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:14', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'd84f69c0-e149-4415-97b5-3e68b6224217'	System	06 Sep 2020 05:51:16
User entered '06 Sep 2020 00:51'	System	06 Sep 2020 05:51:16

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 7'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:41:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '29446f30-2198-4e33-8654-4a897e27e232'	System	07 Sep 2020 05:44:36
User entered 'Yes (Y)'	System	07 Sep 2020 05:44:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '29446f30-2198-4e33-8654-4a897e27e232'	System	07 Sep 2020 05:44:36
User entered '97.9'	System	07 Sep 2020 05:44:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:26', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '29446f30-2198-4e33-8654-4a897e27e232'	System	07 Sep 2020 05:44:36
User entered 'No (N)'	System	07 Sep 2020 05:44:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:33', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '29446f30-2198-4e33-8654-4a897e27e232'	System	07 Sep 2020 05:44:36
User entered '07 Sep 2020 00:44'	System	07 Sep 2020 05:44:36

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '73deef10-875c-499c-ad64-f59c4f6d1d1a'	System	31 Aug 2020 19:55:30
User entered 'None (1)'	System	31 Aug 2020 19:55:30

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '73deef10-875c-499c-ad64-f59c4f6d1d1a'	System	31 Aug 2020 19:55:30
User entered 'No (N)'	System	31 Aug 2020 19:55:30

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '73deef10-875c-499c-ad64-f59c4f6d1d1a'	System	31 Aug 2020 19:55:30
User entered 'No (N)'	System	31 Aug 2020 19:55:30

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:22', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '73deef10-875c-499c-ad64-f59c4f6d1d1a'	System	31 Aug 2020 19:55:30
User entered 'None (1)'	System	31 Aug 2020 19:55:30

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:28', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '73deef10-875c-499c-ad64-f59c4f6d1d1a'	System	31 Aug 2020 19:55:30
User entered '31 Aug 2020 14:55'	System	31 Aug 2020 19:55:30

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 14:42'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 17:12'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:12', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '449d6b00-dc2c-4881-9d31-85213a5b65f1'	System	01 Sep 2020 02:37:47
User entered 'None (1)'	System	01 Sep 2020 02:37:47

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '449d6b00-dc2c-4881-9d31-85213a5b65f1'	System	01 Sep 2020 02:37:47
User entered 'No (N)'	System	01 Sep 2020 02:37:47

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:22', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '449d6b00-dc2c-4881-9d31-85213a5b65f1'	System	01 Sep 2020 02:37:47
User entered 'No (N)'	System	01 Sep 2020 02:37:47

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:27', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '449d6b00-dc2c-4881-9d31-85213a5b65f1'	System	01 Sep 2020 02:37:47
User entered 'None (1)'	System	01 Sep 2020 02:37:47

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:43', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '449d6b00-dc2c-4881-9d31-85213a5b65f1'	System	01 Sep 2020 02:37:47
User entered '31 Aug 2020 21:37'	System	01 Sep 2020 02:37:47

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 18:07'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 2'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'dd1e036c-af47-42ae-9eba-c347060b1956'	System	02 Sep 2020 04:29:36
User entered 'None (1)'	System	02 Sep 2020 04:29:36

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:17', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'dd1e036c-af47-42ae-9eba-c347060b1956'	System	02 Sep 2020 04:29:36
User entered 'No (N)'	System	02 Sep 2020 04:29:36

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'dd1e036c-af47-42ae-9eba-c347060b1956'	System	02 Sep 2020 04:29:36
User entered 'No (N)'	System	02 Sep 2020 04:29:36

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'dd1e036c-af47-42ae-9eba-c347060b1956'	System	02 Sep 2020 04:29:36
User entered 'None (1)'	System	02 Sep 2020 04:29:36

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:33', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'dd1e036c-af47-42ae-9eba-c347060b1956'	System	02 Sep 2020 04:29:36
User entered '01 Sep 2020 23:29'	System	02 Sep 2020 04:29:36

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 3'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:36', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '62c0177f-8d6f-43f0-add2-06eadaa5c2c4'	System	03 Sep 2020 03:38:55
User entered 'None (1)'	System	03 Sep 2020 03:38:55

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:40', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '62c0177f-8d6f-43f0-add2-06eadaa5c2c4'	System	03 Sep 2020 03:38:55
User entered 'No (N)'	System	03 Sep 2020 03:38:55

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:44', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '62c0177f-8d6f-43f0-add2-06eadaa5c2c4'	System	03 Sep 2020 03:38:55
User entered 'No (N)'	System	03 Sep 2020 03:38:55

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '62c0177f-8d6f-43f0-add2-06eadaa5c2c4'	System	03 Sep 2020 03:38:55
User entered 'None (1)'	System	03 Sep 2020 03:38:55

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:52', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '62c0177f-8d6f-43f0-add2-06eadaa5c2c4'	System	03 Sep 2020 03:38:55
User entered '02 Sep 2020 22:38'	System	03 Sep 2020 03:38:55

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 4'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:20', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '865a2ea7-5a58-40d1-946e-e4dfbd94b127'	System	04 Sep 2020 04:39:50
User entered 'None (1)'	System	04 Sep 2020 04:39:50

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:28', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '865a2ea7-5a58-40d1-946e-e4dfbd94b127'	System	04 Sep 2020 04:39:50
User entered 'No (N)'	System	04 Sep 2020 04:39:50

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:35', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '865a2ea7-5a58-40d1-946e-e4dfbd94b127'	System	04 Sep 2020 04:39:50
User entered 'No (N)'	System	04 Sep 2020 04:39:50

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '865a2ea7-5a58-40d1-946e-e4dfbd94b127'	System	04 Sep 2020 04:39:50
User entered 'None (1)'	System	04 Sep 2020 04:39:50

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:47', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '865a2ea7-5a58-40d1-946e-e4dfbd94b127'	System	04 Sep 2020 04:39:50
User entered '03 Sep 2020 23:39'	System	04 Sep 2020 04:39:50

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 5'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:49', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7dc85b96-3506-4439-acb8-fb98b8a6e4e2'	System	05 Sep 2020 05:56:08
User entered 'None (1)'	System	05 Sep 2020 05:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7dc85b96-3506-4439-acb8-fb98b8a6e4e2'	System	05 Sep 2020 05:56:08
User entered 'No (N)'	System	05 Sep 2020 05:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7dc85b96-3506-4439-acb8-fb98b8a6e4e2'	System	05 Sep 2020 05:56:08
User entered 'No (N)'	System	05 Sep 2020 05:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:55:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7dc85b96-3506-4439-acb8-fb98b8a6e4e2'	System	05 Sep 2020 05:56:08
User entered 'None (1)'	System	05 Sep 2020 05:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7dc85b96-3506-4439-acb8-fb98b8a6e4e2'	System	05 Sep 2020 05:56:08
User entered '05 Sep 2020 00:56'	System	05 Sep 2020 05:56:08

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 6'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:18', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'fcb47170-97a4-4975-90ad-610ab5c75513'	System	06 Sep 2020 05:51:35
User entered 'None (1)'	System	06 Sep 2020 05:51:35

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:22', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'fcb47170-97a4-4975-90ad-610ab5c75513'	System	06 Sep 2020 05:51:35
User entered 'No (N)'	System	06 Sep 2020 05:51:35

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:24', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'fcb47170-97a4-4975-90ad-610ab5c75513'	System	06 Sep 2020 05:51:35
User entered 'No (N)'	System	06 Sep 2020 05:51:35

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:27', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'fcb47170-97a4-4975-90ad-610ab5c75513'	System	06 Sep 2020 05:51:35
User entered 'None (1)'	System	06 Sep 2020 05:51:35

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:32', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'fcb47170-97a4-4975-90ad-610ab5c75513'	System	06 Sep 2020 05:51:35
User entered '06 Sep 2020 00:51'	System	06 Sep 2020 05:51:35

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 7'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:43', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b9e4c07-ab9a-41ea-bf19-c302f2c7384f'	System	07 Sep 2020 05:45:06
User entered 'None (1)'	System	07 Sep 2020 05:45:06

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b9e4c07-ab9a-41ea-bf19-c302f2c7384f'	System	07 Sep 2020 05:45:06
User entered 'No (N)'	System	07 Sep 2020 05:45:06

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:49', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b9e4c07-ab9a-41ea-bf19-c302f2c7384f'	System	07 Sep 2020 05:45:06
User entered 'No (N)'	System	07 Sep 2020 05:45:06

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:44:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b9e4c07-ab9a-41ea-bf19-c302f2c7384f'	System	07 Sep 2020 05:45:06
User entered 'None (1)'	System	07 Sep 2020 05:45:06

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '7b9e4c07-ab9a-41ea-bf19-c302f2c7384f' User entered '07 Sep 2020 00:45'	System	07 Sep 2020 05:45:06
	System	07 Sep 2020 05:45:06

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:37', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:39', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:41', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:43', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'None (0)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:55:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered 'No (N)'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T14:56:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b9844fb6-09b7-4ad6-8d53-fd00f27f9e84'	System	31 Aug 2020 19:56:04
User entered '31 Aug 2020 14:56'	System	31 Aug 2020 19:56:04

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 14:42'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 17:12'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'None (0)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:52', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'None (0)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:54', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'None (0)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'None (0)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:37:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:38:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'None (0)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:38:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered 'No (N)'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-08-31T21:38:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'c83553a2-3a66-4228-a7a0-1d13d6351729'	System	01 Sep 2020 02:38:19
User entered '31 Aug 2020 21:38'	System	01 Sep 2020 02:38:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '31 Aug 2020 18:07'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 2'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:56', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:29:58', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:30:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:30:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:30:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:30:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'None (0)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:31:03', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered 'No (N)'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-01T23:31:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'aeb773fc-c5cc-41b9-8607-67a170b7f0b9'	System	02 Sep 2020 04:31:19
User entered '01 Sep 2020 23:31'	System	02 Sep 2020 04:31:19

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 3'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:38:58', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:04', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:06', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:08', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'None (0)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:12', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered 'No (N)'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-02T22:39:18', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'b156e7b8-379e-43ef-819b-d87010f9e6e2'	System	03 Sep 2020 03:39:20
User entered '02 Sep 2020 22:39'	System	03 Sep 2020 03:39:20

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 4'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:54', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:55', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:39:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:40:00', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:40:02', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'None (0)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:40:06', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered 'No (N)'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-03T23:40:12', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f3ff2822-2057-4a94-85b5-754429bb4355'	System	04 Sep 2020 04:40:16
User entered '03 Sep 2020 23:40'	System	04 Sep 2020 04:40:16

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 5'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:15', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:17', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:19', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:21', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:25', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'None (0)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:28', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered 'No (N)'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-05T00:56:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '83d34a81-204a-410f-a16b-b87e6854d393'	System	05 Sep 2020 05:56:40
User entered '05 Sep 2020 00:56'	System	05 Sep 2020 05:56:40

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 6'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:38', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:40', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:42', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:44', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'None (0)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:51', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered 'No (N)'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-06T00:51:57', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'e47c6b53-10cd-4341-a292-bf24d5f45f55'	System	06 Sep 2020 05:51:59
User entered '06 Sep 2020 00:51'	System	06 Sep 2020 05:51:59

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	31 Aug 2020 19:53:21
User entered 'Day 7'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:10', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:12', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:14', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:16', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:18', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'None (0)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:26', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered 'No (N)'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-09-07T00:45:34', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '797fcad7-313b-41de-9754-b72a4e21c457'	System	07 Sep 2020 05:45:36
User entered '07 Sep 2020 00:45'	System	07 Sep 2020 05:45:36

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 19:53:21

US3812060

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 09:52:46

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 19:53:21

US3812060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 13:56:37

US3812060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '9 Sep 2020'	Karen Knapp (b) (4)	09 Sep 2020 13:56:37

US3812060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Sep 2020 13:56:37

US3812060

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	09 Sep 2020 13:56:37

US3812060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	13 Sep 2020 14:13:41

US3812060

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	13 Sep 2020 14:13:41

US3812060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 14:26:30

US3812060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '15 Sep 2020'	Karen Knapp (b) (4)	15 Sep 2020 14:26:30

US3812060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	15 Sep 2020 14:26:30

US3812060

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	15 Sep 2020 14:26:30

US3812060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	15 Sep 2020 14:26:35

US3812060

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	15 Sep 2020 14:26:35

US3812060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Sep 2020 17:14:00

US3812060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '21 Sep 2020'	Karen Knapp (b) (4)	21 Sep 2020 17:14:00

US3812060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	21 Sep 2020 17:14:00

US3812060

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Karen Knapp (b) (4)	21 Sep 2020 17:14:00

US3812060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	21 Sep 2020 17:14:04

US3812060

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	21 Sep 2020 17:14:04

US3812060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:31

US3812060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:31

US3812060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:31

US3812060

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'VISIT3'	System	29 Sep 2020 21:27:31

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '14:46'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '29 Sep 2020 14:46'	System	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '96.8' F	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered empty.	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '67'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '18'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '116'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '80'	Breanna Galibert (b) (4)	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	29 Sep 2020 21:27:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	29 Sep 2020 21:28:02

US3812060

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	29 Sep 2020 21:28:02

US3812060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	29 Sep 2020 21:28:20

US3812060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	29 Sep 2020 21:28:20

US3812060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered '15:00'	Breanna Galibert (b) (4)	29 Sep 2020 21:28:20

US3812060

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:52:46

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '29 Sep 2020 15:00'	System	29 Sep 2020 21:28:20

US3812060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:30
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 15:28:51

US3812060

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	18 Oct 2020 15:28:51

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 64'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-08T18:01:37', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f95293e8-748c-44d7-bb62-fa7f765494a3'	System	08 Oct 2020 23:01:51
User entered 'No (N)'	System	08 Oct 2020 23:01:51

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-08T18:01:42', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f95293e8-748c-44d7-bb62-fa7f765494a3'	System	08 Oct 2020 23:01:51
User entered 'No (N)'	System	08 Oct 2020 23:01:51

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-08T18:01:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: 'f95293e8-748c-44d7-bb62-fa7f765494a3' User entered '08 Oct 2020 18:01:48'	System	08 Oct 2020 23:01:51
	System	08 Oct 2020 23:01:51

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '06 Oct 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '10 Oct 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 71'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-14T13:00:37', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '52c6db7c-b9e1-4aac-924c-feb69b5693c7'	System	14 Oct 2020 18:00:57
User entered 'No (N)'	System	14 Oct 2020 18:00:57

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-14T13:00:48', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '52c6db7c-b9e1-4aac-924c-feb69b5693c7'	System	14 Oct 2020 18:00:57
User entered 'No (N)'	System	14 Oct 2020 18:00:57

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-14T13:00:53', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '52c6db7c-b9e1-4aac-924c-feb69b5693c7' User entered '14 Oct 2020 13:00:53'	System	14 Oct 2020 18:00:57
	System	14 Oct 2020 18:00:57

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '13 Oct 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '17 Oct 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 78'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T16:21:03', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'Yes (Y)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:06:11', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'No (N)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject was assessed and entered convalescent period for illness visits. No AE required, recorded on symptom log' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 04:59:11
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Subject was assessed and entered convalescent period for illness visits. No AE required, recorded on symptom log' (Site from DM).	Angie Kean (b) (4) (b) (4)	01 Dec 2020 20:39:51
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:28:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:06:31', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'Yes (Y)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '1'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '1'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:07', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered '0'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:13', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:29', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'Yes (Y)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:33', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77'	System	23 Oct 2020 22:07:58
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-10-23T17:07:46', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '58db030c-b502-4b98-acac-613d70c61b77' User entered '23 Oct 2020 17:07:46'	System	23 Oct 2020 22:07:58
	System	23 Oct 2020 22:07:58

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '20 Oct 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '24 Oct 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 92'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-11-05T18:27:59', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '86a80a6a-af31-41d7-aab9-26b1a49d2242'	System	06 Nov 2020 00:28:15
User entered 'No (N)'	System	06 Nov 2020 00:28:15

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-11-05T18:28:05', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '86a80a6a-af31-41d7-aab9-26b1a49d2242'	System	06 Nov 2020 00:28:15
User entered 'No (N)'	System	06 Nov 2020 00:28:15

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (bb766381e9f5b658)', Time: '2020-11-05T18:28:11', User OID: 'PatientReportedOutcome (US3812060)', ODM File OID: '86a80a6a-af31-41d7-aab9-26b1a49d2242'	System	06 Nov 2020 00:28:15
User entered '05 Nov 2020 18:28:11'	System	06 Nov 2020 00:28:15

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '03 Nov 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:41:21
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '07 Nov 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 99'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Have you been exposed to someone with 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

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Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '10 Nov 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '14 Nov 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered 'Day 106'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Have you been exposed to someone with 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '17 Nov 2020 00:01'	System	06 Aug 2020 16:57:29

US3812060

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 14:40:24
Data entry locked.	System	06 Aug 2020 16:57:29
User entered '21 Nov 2020 23:59'	System	06 Aug 2020 16:57:29

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 14:40:24

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 14:40:24

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 14:40:24

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 14:40:24

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Have you been exposed to someone with 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Please 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 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 14:40:24

US3812060

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:52:46

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
Amendment Manager: Data entry locked.	System	19 Nov 2020 14:40:24
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 14:40:24

US3812060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4)	24 Dec 2020 17:36:59
User entered 'Yes (Y)'	Karen Knapp (b) (4)	27 Oct 2020 15:36:52

US3812060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	24 Dec 2020 17:36:59
User entered '27 Oct 2020'	Karen Knapp (b) (4)	27 Oct 2020 15:36:52

US3812060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4)	24 Dec 2020 17:36:59
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	27 Oct 2020 15:36:52

US3812060

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'SUBJECT IN CONVALESCENT PERIOD' reason for change: New Information	Angie Kean (b) (4)	24 Dec 2020 17:36:59
User entered empty.	Karen Knapp (b) (4)	27 Oct 2020 15:36:52

US3812060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Karen Knapp (b) (4)	27 Oct 2020 15:36:56

US3812060

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	27 Oct 2020 15:36:56

US3812060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Angie Kean (b) (4)	11 Dec 2020 23:55:25

US3812060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Angie Kean (b) (4)	11 Dec 2020 23:55:25

US3812060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Angie Kean (b) (4)	11 Dec 2020 23:55:25

US3812060

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:52:46

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Subject expired, see SAE'	Angie Kean (b) (4)	11 Dec 2020 23:55:25

US3812060

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Angie Kean (b) (4)	11 Dec 2020 23:55:31

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Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:52:46

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	11 Dec 2020 23:55:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:46

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:02

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:46

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '12:20'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:02

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:46

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '26 Oct 2020 12:20'	System	27 Oct 2020 21:35:02

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:46

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:02

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:52:46

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:07
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:02

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 1 (Day 1)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-10. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 08:45:32
Query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-10. If not collected, please consider recording these as Not Done. ' answered with 'updated' (Site from DM).	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 18:11:27
User entered missing code ND - Not Done; reason for change Per Query Resolution	Breanna Galibert (b) (4) (b) (4)	18 Jan 2021 18:11:14
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing for Days 1-10. If not collected, please consider recording these as Not Done. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 13:35:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:31

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 2 (Day 2)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Angie Kean (b) (4)	24 Dec 2020 17:29:07
User entered 'None (None)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	27 Oct 2020 21:37:11
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:35:54

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 3 (Day 3)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Form: Symptom Log (3)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Angie Kean (b) (4)	24 Dec 2020 17:29:18
User entered 'None (None)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	27 Oct 2020 21:37:02
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:15

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Form: Symptom Log (4)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 4 (Day 4)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:36:47

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 5 (Day 5)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '20 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07
	(b) (4)	

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Moderate (Moderate)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:07

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 6 (Day 6)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '21 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21
	(b) (4)	

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (6)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:21

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 7 (Day 7)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '22 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (7)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:34

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 8 (Day 8)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '23 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (8)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:38:48

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 9 (Day 9)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '24 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (9)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 10 (Day 10)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '25 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	18 Jan 2021 18:11:14
User entered empty.	System	27 Oct 2020 21:39:20

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered missing code ND - Not Done; reason for change Per Query Resolution	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	18 Jan 2021 18:11:14
	(b) (4)	
	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20
	(b) (4)	

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (10)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:20

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 11 (Day 11)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '98'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '97.2' F	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (11)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	27 Oct 2020 21:39:39

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 12 (Day 12)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '27 Oct 2020'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '98'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '97.6' F	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (12)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:30

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Day 13 (Day 13)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. However, on Symptom Log, Symptom Day 13 is recorded as 28Oct2020. Therefore, please verify data and update all applicable forms and data-fields as appropriate, since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 14:11:56
Query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. However, on Symptom Log, Symptom Day 13 is recorded as 28Oct2020. Therefore, please verify data and update all applicable forms and data-fields as appropriate, since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' answered with 'UPDATED NARRATIVE TO REFLECT CORRECT CONTACT DATES' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:32:10
User opened query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. However, on Symptom Log, Symptom Day 13 is recorded as 28Oct2020. Therefore, please verify data and update all applicable forms and data-fields as appropriate, since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:51:46
User entered '28 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '100'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '%'	System	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '97.6' F	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: Symptom Log (13)

Generated On: 10 Jun 2021 09:52:46

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'None (None)'	Breanna Galibert (b) (4)	03 Nov 2020 18:25:52

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[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)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:33
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:40:06

US3812060

Folder: Covid-19 Assessment 26 Oct 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 09:52:46

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '0'	System	27 Oct 2020 21:40:06

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Folder: Covid-19 Assessment 26 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:52:46

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:54:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:11

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 3 (Day 3)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:24:42
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User closed query 'Per CDM Re-query: Site response indicates 'Narrative' on Log Line 2 of AE form was updated to reflect correct contact date, however, it appears the dates are still out of sequence. Please verify data, specifically the sequence of dates and the timeline, and consider making the following updates if appropriate: (1) update 'Date of Collection' on this 'Saliva Collection' form to '26Oct2020' if that is when Illness visit took place; (2) if last contact with subject was during phone call to notify subject of negative test during Safety Call Day 85, please ensure this last contact is reflected in data on Safety Call Day 85 form; (3) update 'Narrative' on Log Line 2 of AE form to reflect last date of contact is 28Oct2020 if this is the date of Safety Call Day 85 when subject was notified of negative test. Please update accordingly, or reach out to PI for further clarification. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) Lyly Dang (b) (4)	05 Apr 2021 13:47:22 26 Mar 2021 19:31:39

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Query 'Per CDM Re-query: Site response indicates 'Narrative' on Log Line 2 of AE form was updated to reflect correct contact date, however, it appears the dates are still out of sequence. Please verify data, specifically the sequence of dates and the timeline, and consider making the following updates if appropriate: (1) update 'Date of Collection' on this 'Saliva Collection' form to '26Oct2020' if that is when Illness visit took place; (2) if last contact with subject was during phone call to notify subject of negative test during Safety Call Day 85, please ensure this last contact is reflected in data on Safety Call Day 85 form; (3) update 'Narrative' on Log Line 2 of AE form to reflect last date of contact is 28Oct2020 if this is the date of Safety Call Day 85 when subject was notified of negative test. Please update accordingly, or reach out to PI for further clarification. Thank you.' answered with 'Please note, illness day 1 was on 26 OCT 2020. The subject collected day 3 saliva on 28 OCT 2020, which is correct in EDC. The site notified subject of negative covid swab on 29 OCT 2020. ' (Site from DM). User opened query 'Per CDM Re-query: Site response indicates 'Narrative' on Log Line 2 of AE form was updated to reflect correct contact date, however, it appears the dates are still out of sequence. Please verify data, specifically the sequence of dates and the timeline, and consider making the following updates if appropriate: (1) update 'Date of Collection' on this 'Saliva Collection' form to '26Oct2020' if that is when Illness visit took place; (2) if last contact with subject was during phone call to notify subject of negative test during Safety Call Day 85, please ensure this last contact is reflected in data on Safety Call Day 85 form; (3) update 'Narrative' on Log Line 2 of AE form to reflect last date of contact is 28Oct2020 if this is the date of Safety Call Day 85 when subject was notified of negative test. Please update accordingly, or reach out to PI for further clarification. Thank you.' (Site from DM).	Angie Kean (b) (4) (b) (4)	25 Mar 2021 21:22:32
	(b) (4), (b) (6)	21 Jan 2021 19:44:49

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. Therefore, please verify and update data-fields on 'Saliva Collection' form for 'Was Saliva Collected' and 'Date of Collection', since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 07:23:17
Query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. Therefore, please verify and update data-fields on 'Saliva Collection' form for 'Was Saliva Collected' and 'Date of Collection', since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' answered with 'UPDATED NARRATIVE TO REFLECT CORRECT CONTACT DATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:32:32
User opened query 'Per CDM: Per Log Line 2 of AE form, recorded in 'Narrative', site reports that site's last successful contact with subject was on 27Oct2020 for a D85 Safety Phone Call. Therefore, please verify and update data-fields on 'Saliva Collection' form for 'Was Saliva Collected' and 'Date of Collection', since 28Oct2020 is after 27Oct2020, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:44:14
User entered '28 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4) (b) (4)	03 Nov 2020 18:24:42
User entered empty.	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 5 (Day 5)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 7 (Day 7)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 9 (Day 9)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 14 (Day 14)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 21 (Day 21)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User accepted default value 'Day 28 (Day 28)'	Breanna Galibert (b) (4) (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:46

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'NA (COVID-19 Negative) (NA)' reason for change: New Information	Breanna Galibert (b) (4)	03 Nov 2020 18:26:25
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:55:18
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:32:14

US3812060

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:00:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:00:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:00:06
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'SICKD1'	System	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '12:40'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '26 Oct 2020 12:40'	System	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '68.0' in	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54
DataPoint set to visible.	System	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '174.0' lb	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54
DataPoint set to visible.	System	27 Oct 2020 21:40:21

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '97.2' F	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '76'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'bpm'	System	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '14'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'breaths/min'	System	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '118'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 21:56:28
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '70'	Breanna Galibert (b) (4)	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered 'mmHg'	System	27 Oct 2020 21:40:54

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	26 Apr 2021 21:20:50

US3812060

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:38:02
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:41:09

US3812060

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:38:02
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:41:09

US3812060

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:52:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:47:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	27 Oct 2020 21:42:11

US3812060

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:47:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '26 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:42:11

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:36:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 11:22:09
Query 'Data is required. Please complete.' answered with 'please inactivate page per other queries received on (-) results and information provided on this page' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 17:53:51
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:53:49
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 17:53:49
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 17:53:49
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 17:53:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	31 Oct 2020 17:31:49
User entered 'No (N)' reason for change: Data Entry Error	Breanna Galibert (b) (4)	31 Oct 2020 17:31:49
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	31 Oct 2020 17:31:44
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	31 Oct 2020 17:31:44

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:44

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:51
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Visit was performed, however, Was visit performed at home or clinic is missing. Please review and reconcile.' (Site from System).	System	31 Oct 2020 17:31:49
User entered empty.	System	31 Oct 2020 17:31:44
	Breanna Galibert (b) (4)	31 Oct 2020 17:31:44
	(b) (4)	

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:52:46

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	21 Apr 2021 17:53:49
User entered 'SICKD28'	System	31 Oct 2020 17:31:44

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:36:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 11:22:12
Query 'Data is required. Please complete.' answered with 'please inactivate page per other queries received on (-) results and information provided on this page' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 17:53:59
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:53:56
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 17:53:56
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 17:53:56
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 17:53:56
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	31 Oct 2020 17:31:51

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

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Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:54
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	31 Oct 2020 17:31:51

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:52:46

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:36:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 11:22:15
Query 'Data is required. Please complete.' answered with 'please inactivate page per other queries received on (-) results and information provided on this page' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 17:54:13
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:54:11
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 17:54:11
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 17:54:11
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 17:54:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'No (N)'	Breanna Galibert (b) (4)	31 Oct 2020 17:31:53

US3812060

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:52:46

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:50:59
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:53

US3812060

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:52:46

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Apr 2021 15:36:39
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 11:22:19
Query 'Data is required. Please complete.' answered with 'please inactivate page per other queries received on (-) results and information provided on this page' (Site from System).	Breanna Galibert (b) (4)	21 Apr 2021 17:54:07
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 17:54:05
DataPoint Un-verified.	Breanna Galibert (b) (4)	21 Apr 2021 17:54:05
Signature has been broken.	Breanna Galibert (b) (4)	21 Apr 2021 17:54:05
User entered empty; reason for change Data Entry Error	Breanna Galibert (b) (4)	21 Apr 2021 17:54:05
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:51:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'NA (COVID-19 Negative) (NA)'	Breanna Galibert (b) (4)	31 Oct 2020 17:31:55

US3812060

Folder: Convalescence Visit Day 28 (1)

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

Generated On: 10 Jun 2021 09:52:46

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:51:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Breanna Galibert (b) (4)	31 Oct 2020 17:31:55

US3812060

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:52:46

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User closed query 'Per CDM: On AE Log Line 2, Grade 4 SAE 'Death' is recorded on 30Nov2020. In Narrative of this AE form, site reports: 'Site's last successful contact with subject was on 29Oct2020, when subject was notified of Negative Covid-19 swab', however, please note, there is a Safety Follow Up Diary (1) 'Timepoint Day 92' form that was completed on 05Nov2020. Please verify data and either clarify, or reconcile data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:30:31
Query 'Per CDM: On AE Log Line 2, Grade 4 SAE 'Death' is recorded on 30Nov2020. In Narrative of this AE form, site reports: 'Site's last successful contact with subject was on 29Oct2020, when subject was notified of Negative Covid-19 swab', however, please note, there is a Safety Follow Up Diary (1) 'Timepoint Day 92' form that was completed on 05Nov2020. Please verify data and either clarify, or reconcile data as appropriate. Thank you.' answered with 'Although subject completed e-diary entry on 05 NOV 2020, the last contact site had with subject was 29 OCT 2020. Data is correct' (Site from DM).	Angie Kean (b) (4)	25 Mar 2021 21:13:15
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:28:35
User opened query 'Per CDM: On AE Log Line 2, Grade 4 SAE 'Death' is recorded on 30Nov2020. In Narrative of this AE form, site reports: 'Site's last successful contact with subject was on 29Oct2020, when subject was notified of Negative Covid-19 swab', however, please note, there is a Safety Follow Up Diary (1) 'Timepoint Day 92' form that was completed on 05Nov2020. Please verify data and either clarify, or reconcile data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 19:13:25
User entered 'Yes (Y)'	Karen Knapp (b) (4)	03 Sep 2020 12:37:38

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Styte - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 09:09:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	02 Oct 2020 09:09:42
Data point term sent to Coder	System	01 Oct 2020 18:59:05
User entered 'RIGHT EYE STYE'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '29 Sep 2020'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User entered empty.	System	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	27 Oct 2020 21:42:53
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '01 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	27 Oct 2020 21:42:53
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User entered empty.	System	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'Grade 1/Mild (Grade 1/Mild)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

US3812060

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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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)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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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)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '1'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered '0'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Breanna Galibert (b) (4)	27 Oct 2020 21:42:53
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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Folder: Adverse Events

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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 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 21:36:16
User entered empty.	Breanna Galibert (b) (4)	01 Oct 2020 18:58:32

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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 15:17:21
User entered '0'	System	01 Oct 2020 18:58:32

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Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21
User entered '0'	System	01 Oct 2020 18:58:32

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Folder: Adverse Events

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:17:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:58:39
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:52:13
User entered	System	05 Dec 2020 17:52:09
'USA-US111-2020-mRNA-1273-P301000017'		
User entered 'New'	(b) (4), (b) (6)	05 Dec 2020 17:52:09

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:28:59
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death when information is available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:23:14
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 18:07:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	25 Mar 2021 18:07:29
	(b) (4)	
Data point term sent to Coder	System	25 Mar 2021 18:06:25
User closed query 'For coding purposes, AE term DEATH is recorded. Death is an outcome and generally not a adverse event. Please provide the underlying diagnosis. If unknown, please specify. ' (Site from System).	System	25 Mar 2021 18:06:03
Query 'For coding purposes, AE term DEATH is recorded. Death is an outcome and generally not a adverse event. Please provide the underlying diagnosis. If unknown, please specify. ' answered with 'updated' (Site from System).	Lyly Dang (b) (4)	25 Mar 2021 18:06:03
Query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death when information is available.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	25 Mar 2021 18:05:58
DataPoint Un-verified.	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
Coding entries removed.	Lyly Dang (b) (4)	25 Mar 2021 18:05:50

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[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Myocardial infarction' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
User opened query 'For coding purposes, AE term DEATH is recorded. Death is an outcome and generally not a adverse event. Please provide the underlying diagnosis. If unknown, please specify. ' (Site from System). DataPoint Verified.	Coder Import (b) (4)	16 Mar 2021 17:19:53
	(b) (4), (b) (6)	30 Dec 2020 18:58:41
User opened query 'PV Query: Thank you for reporting the event of death. Please note that death is an outcome; please consider updating the event term to the underlying cause of death when information is available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:37:41
User coded data point as SOC: General disorders and administration site conditions, HLGT: Fatal outcomes, HLT: Death and sudden death, PT: Death, LLT: Death - version MedDRA\23.0.	Coder Import (b) (4)	05 Dec 2020 01:02:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Dec 2020 01:02:03
Data point term sent to Coder	System	05 Dec 2020 01:01:44
User entered 'Death'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 19:57:45
Query 'Data is required. Please complete.' answered with 'unknown at this time' (Site from System).	Lyly Dang (b) (4)	05 Dec 2020 01:03:05
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:01:11
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:12
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:02:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Dec 2020 01:02:32
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Dec 2020 01:02:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:01:11
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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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)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:14
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	08 Dec 2020 19:57:47
Query 'Data is required. Please complete.' answered with 'Unknown at this time' (Site from System).	Lyly Dang (b) (4)	05 Dec 2020 01:01:37
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:01:11
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:25
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Un-verified.	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
User entered '24 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:16
Query 'PV Query: Please provide the onset date for the event.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:47:40
User opened query 'PV Query: Please provide the onset date for the event.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:41:37
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Dec 2020 01:03:35
User entered '30 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Dec 2020 01:03:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Dec 2020 01:02:32
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:02:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Dec 2020 01:02:32
User entered 'un Nov 2020' (non-conformant).	Lyly Dang (b) (4)	05 Dec 2020 01:02:32
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Dec 2020 01:01:11
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:18
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered empty.	System	05 Dec 2020 01:01:11

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:21
User entered 'No (N)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:29:27
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Un-verified.	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
User entered '24 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:20
Query 'PV Query: Please provide subject's exact date of death when available (reported as ??-Nov-2020).' canceled (Site from Safety).	(b) (4), (b) (6)	29 Dec 2020 16:47:24
User opened query 'PV Query: Please provide subject's exact date of death when available (reported as ??-Nov-2020).' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:40:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Dec 2020 01:03:35
User entered '30 Nov 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Dec 2020 01:03:35
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Dec 2020 01:02:32
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Dec 2020 01:02:32
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	05 Dec 2020 01:02:32
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Dec 2020 01:02:32
User entered 'un Nov 2020' (non-conformant).	Lyly Dang (b) (4)	05 Dec 2020 01:02:32

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	05 Dec 2020 01:01:11
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	05 Dec 2020 01:01:11
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 18:59:50
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered empty.	System	05 Dec 2020 01:01:11

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:10
User entered 'Grade 4 (Grade 4)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:11
User entered 'Yes (Y)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:13
User entered '1'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:15
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:17
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

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Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:18
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:20
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:48
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:47
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:46
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:44
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

US3812060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:42
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:40
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

US3812060

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 15:07:23
User closed query 'Please clarify as Source notes N/A.' (Site from CRA).	(b) (4), (b) (6)	27 Apr 2021 15:06:49
Query 'Please clarify as Source notes N/A.' answered with 'PI originally determined relationship to study procedure was NOT RELATED. Per DM query, this was changed to NA as instructed. Now, DM has again requested this to be determined related or not related. PI confirms NOT RELATED.' (Site from CRA).	Angie Kean (b) (4)	23 Apr 2021 20:24:27
User opened query 'Please clarify as Source notes N/A.' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 20:30:25
User signature succeeded.	Lyly Dang (b) (4)	12 Apr 2021 15:03:03
User closed query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received study drug, please update relatedness to study procedure to related or not related.' (Site from Safety).	(b) (4), (b) (6)	09 Apr 2021 14:09:52
Query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received study drug, please update relatedness to study procedure to related or not related.' answered with 'updated' (Site from Safety).	Angie Kean (b) (4)	08 Apr 2021 22:39:02
Signature has been broken.	Angie Kean (b) (4)	08 Apr 2021 22:38:42
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Angie Kean (b) (4)	08 Apr 2021 22:38:42
User opened query 'PV Query: Relatedness to study procedure was reported as not applicable. As subject received study drug, please update relatedness to study procedure to related or not related.' (Site from Safety).	(b) (4), (b) (6)	06 Apr 2021 12:59:49

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Please verify if subject received the study drug. If no, this should be not applicable. If yes, this should be Related or Not Related. Please confirm correct or update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 11:47:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Query 'Per CDM: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Please verify if subject received the study drug. If no, this should be not applicable. If yes, this should be Related or Not Related. Please confirm correct or update accordingly. Thank you.' answered with 'ok' (Site from DM).	Lyly Dang (b) (4)	25 Mar 2021 18:06:08
DataPoint Un-verified.	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lyly Dang (b) (4)	25 Mar 2021 18:05:50
User opened query 'Per CDM: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Please verify if subject received the study drug. If no, this should be not applicable. If yes, this should be Related or Not Related. Please confirm correct or update accordingly. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 16:22:18
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:38
User entered 'Not Related (NOT RELATED)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:36
User entered 'Not Applicable (NOT APPLICABLE)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:34
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Dec 2020 01:02:32
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	05 Dec 2020 01:02:32
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Dec 2020 01:01:11
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:53
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:55
User entered '0'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:00:58
User entered 'Fatal (FATAL)'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

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 17:53:51
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
DataPoint Verified.	(b) (4), (b) (6)	30 Dec 2020 19:01:05
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:30:45
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'PV Query: Please confirm date of death was 30 Nov 2020.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:23:25
User closed query 'PV Query: Please provide/confirm the cause of death when available.' (Site from Safety).	(b) (4), (b) (6)	26 Mar 2021 18:23:23
Query 'PV Query: Please confirm date of death was 30 Nov 2020.' answered with 'date of death is confirmed to be 24 Nov 2020' (Site from Safety).	Lyly Dang (b) (4)	25 Mar 2021 18:09:20
Query 'PV Query: Please provide/confirm the cause of death when available.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	25 Mar 2021 18:09:05
DataPoint Un-verified.	Lyly Dang (b) (4)	25 Mar 2021 18:08:39

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE HAS ATTEMPTED TO CONTACT SUBJECT ON MULTIPLE OCCASIONS REGARDING MISSED DIARY ENTRIES AND MISSED D119 SAFETY CALL WITHOUT SUCCESS. SITE'S LAST SUCCESSFUL CONTACT WITH THE SUBJECT WAS ON 29 OCT, 2020 WHEN SUBJECT WAS NOTIFIED OF NEGATIVE COVID-19 SWAB. SITE CALLED THE SUBJECT'S BROTHER, WHO WAS LISTED AS HIS EMERGENCY CONTACT ON 04 DEC 2020 AND PER THE SUBJECT'S BROTHER, THE SUBJECT WAS FOUND DEAD ON NOV 30, 2020 BUT MAY HAVE EXPIRED 1 WEEK PRIOR. SUBJECT'S EXACT DATE OF DEATH AND ETIOLOGY OF DEATH IS UNKNOWN AT THIS TIME. SUBJECT'S DEATH CERTIFICATE WILL BE REQUESTED. SAE WILL BE UPDATED ONCE ADDITIONAL INFORMATION IS AVAILABLE. 25 Mar 2021: Death certificate obtained. Cause of death is probable myocardial infarction. Date of death was noted to be Nov 24, 2020' reason for change: New Information	Lyly Dang (b) (4)	25 Mar 2021 18:08:39
User opened query 'PV Query: Please confirm date of death was 30 Nov 2020.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:52:07
	(b) (4), (b) (6)	30 Dec 2020 19:01:07
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:17:07
User closed query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 18:17:04

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'NO INTERVENTIONS INCLUDING MEDICAL/SURGICAL TREATMENTS.' (Site from Safety).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:14:39
Query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' answered with 'AUTOPSY WAS NOT PERFORMED' (Site from Safety).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:11:57
User entered 'SITE HAS ATTEMPTED TO CONTACT SUBJECT ON MULTIPLE OCCASIONS REGARDING MISSED DIARY ENTRIES AND MISSED D119 SAFETY CALL WITHOUT SUCCESS. SITE'S LAST SUCCESSFUL CONTACT WITH THE SUBJECT WAS ON 29 OCT, 2020 WHEN SUBJECT WAS NOTIFIED OF NEGATIVE COVID-19 SWAB. SITE CALLED THE SUBJECT'S BROTHER, WHO WAS LISTED AS HIS EMERGENCY CONTACT ON 04 DEC 2020 AND PER THE SUBJECT'S BROTHER, THE SUBJECT WAS FOUND DEAD ON NOV 30, 2020 BUT MAY HAVE EXPIRED 1 WEEK PRIOR. SUBJECT'S EXACT DATE OF DEATH AND ETIOLOGY OF DEATH IS UNKNOWN AT THIS TIME. SUBJECT'S DEATH CERTIFICATE WILL BE REQUESTED. SAE WILL BE UPDATED ONCE ADDITIONAL INFORMATION IS AVAILABLE.' reason for change: New Information	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:10:34
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	11 Dec 2020 18:39:49

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide autopsy results if performed. If not performed, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:39:00
User opened query 'PV Query: Please provide/confirm the cause of death when available.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:38:16
User entered 'Site has attempted to contact subject on multiple occasions regarding missed diary entries and missed D119 safety call without success. Site's last successful contact with the subject was on Oct 27, 2020 for a D85 safety phone call. Site called the subject's brother, who was listed as his emergency contact. Per the subject's brother, the subject was found dead on Nov 30, 2020 but may have expired 1 week prior. Subject's exact date of death and etiology of death is unknown at this time. Subject's death certificate will be requested. SAE will be updated once additional information is available.'	Lyly Dang (b) (4)	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

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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 17:53:51
User entered '1'	System	05 Dec 2020 01:01:11

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:52:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: Suspected COVID-19, LLT: Suspected COVID-19 - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 22:28:03
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Apr 2021 22:28:03
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 22:13:22
User entered 'covid-like illness'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered empty.	System	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '21 Oct 2020'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered empty.	System	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'No (N)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '1'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered '0'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

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 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:44:07
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
User entered empty.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered '0'	System	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51
User entered '1'	System	12 Apr 2021 22:13:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:52:46

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:53:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:47:56
User closed query 'Per CDM Re-query: Site response noted. However, per Covid Assessment 'Symptom Log' on Symptom Day 4 (19Oct2020), the response is 'None' to 'Runny Nose (Rhinorrhea)' and there is a CM still recorded on ConMed form for indication 'Runny Nose (Rhinorrhea)' on 19Oct2020. Please reconcile as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 18:23:21
Query 'Per CDM Re-query: Site response noted. However, per Covid Assessment 'Symptom Log' on Symptom Day 4 (19Oct2020), the response is 'None' to 'Runny Nose (Rhinorrhea)' and there is a CM still recorded on ConMed form for indication 'Runny Nose (Rhinorrhea)' on 19Oct2020. Please reconcile as appropriate. Thank you. ' answered with 'Per source, subject reporting taking medication on 19 OCT for runny nose, however also indicated that symptom of runny nose ended on 19 OCT. therefore "NONE" was reported for runny nose on 19 OCT 2020. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	25 Mar 2021 21:25:44
User opened query 'Per CDM Re-query: Site response noted. However, per Covid Assessment 'Symptom Log' on Symptom Day 4 (19Oct2020), the response is 'None' to 'Runny Nose (Rhinorrhea)' and there is a CM still recorded on ConMed form for indication 'Runny Nose (Rhinorrhea)' on 19Oct2020. Please reconcile as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 18:50:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please reconcile the following data on 'ConMed' forms with 'Symptom Log'. (1) Medication 'Zicam' for indication of 'Runny Nose (Rhinorrhea)' is recorded on Log Lines 8 - 10 on ConMed form on 17Oct, 18Oct, and 19Oct, however, on Symptom Log, Subject had moderate 'Runny Nose (Rhinorrhea)' only on 16Oct. (2) Medication 'Tylenol PM' for indication of 'Fatigue' is recorded on Log Lines 11 - 13 on ConMed form on 16Oct, 17Oct, 18Oct, however, on Symptom Log, Subject had 'Fatigue' on 16Oct, 17Oct, 18Oct, 19Oct, 20Oct. (3) There is no medication recorded for moderate 'Nausea' which is recorded on Symptom Log on 17Oct, 18Oct. Kindly verify data as appropriate on all applicable forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 11:50:52
Query 'Per CDM: Please reconcile the following data on 'ConMed' forms with 'Symptom Log'. (1) Medication 'Zicam' for indication of 'Runny Nose (Rhinorrhea)' is recorded on Log Lines 8 - 10 on ConMed form on 17Oct, 18Oct, and 19Oct, however, on Symptom Log, Subject had moderate 'Runny Nose (Rhinorrhea)' only on 16Oct. (2) Medication 'Tylenol PM' for indication of 'Fatigue' is recorded on Log Lines 11 - 13 on ConMed form on 16Oct, 17Oct, 18Oct, however, on Symptom Log, Subject had 'Fatigue' on 16Oct, 17Oct, 18Oct, 19Oct, 20Oct. (3) There is no medication recorded for moderate 'Nausea' which is recorded on Symptom Log on 17Oct, 18Oct. Kindly verify data as appropriate on all applicable forms. Thank you.' answered with 'UPDATED SYMPTOM LOG TO REFLECT RUNNY NOSE FROM 16 OCT THROUGH 18 OCT. PER SUBJECT REPORTING, NO TYLENOL WAS TAKEN ON 19 OCT THROUGH 20 OCT AND NO MEDICATION TAKEN FOR NAUSEA.' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:31:31

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:52:46

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please reconcile the following data on 'ConMed' forms with 'Symptom Log'. (1) Medication 'Zicam' for indication of 'Runny Nose (Rhinorrhea)' is recorded on Log Lines 8 - 10 on ConMed form on 17Oct, 18Oct, and 19Oct, however, on Symptom Log, Subject had moderate 'Runny Nose (Rhinorrhea)' only on 16Oct. (2) Medication 'Tylenol PM' for indication of 'Fatigue' is recorded on Log Lines 11 - 13 on ConMed form on 16Oct, 17Oct, 18Oct, however, on Symptom Log, Subject had 'Fatigue' on 16Oct, 17Oct, 18Oct, 19Oct, 20Oct. (3) There is no medication recorded for moderate 'Nausea' which is recorded on Symptom Log on 17Oct, 18Oct. Kindly verify data as appropriate on all applicable forms. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:34:11
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:25:51

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:29:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:29:02
Data point term sent to Coder User entered 'MULTIVITAMIN'	System Karen Knapp (b) (4)	06 Aug 2020 22:28:11 06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'GENERAL HEALTH'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '2'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Other (OTHER)'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'PACKS'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'twice daily (BID)'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:54:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Megan Dandurand (b) (4)	06 Aug 2020 23:14:08
answered with 'DM error' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:27:39
User entered 'UN Aug 2019'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:14:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:14:22
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:14:22
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:27:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '2'	System	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:27:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:27:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: Please verify the following: (1) Confirm if dosage was divided (i.e. taken at 100mg, 3 times daily, or 150mg, 2 times daily) as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency' data-fields on this form, else clarify, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:35:31
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: BUPROPION HCL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 17:00:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	24 Dec 2020 17:00:26
Query 'Per CDM: Please verify the following: (1) Confirm if dosage was divided (i.e. taken at 100mg, 3 times daily, or 150mg, 2 times daily) as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency' data-fields on this form, else clarify, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' answered with 'Subject reported at screening 300mg QD, information is unable to be verified as subject has expired. ' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:00:18
Data point term sent to Coder	System	24 Dec 2020 16:59:28
Coding entries removed.	Angie Kean (b) (4) (b) (4)	24 Dec 2020 16:59:16
User entered 'BUPROPION HCL' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	24 Dec 2020 16:59:16

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please verify the following: (1) Confirm if dosage was divided (i.e. taken at 100mg, 3 times daily, or 150mg, 2 times daily) as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency' data-fields on this form, else clarify, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:07:08
Query 'Per CDM: Please verify the following: (1) Confirm if dosage was divided (i.e. taken at 100mg, 3 times daily, or 150mg, 2 times daily) as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency' data-fields on this form, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:06:32
User opened query 'Per CDM: Please verify the following: (1) Confirm if dosage was divided (i.e. taken at 100mg, 3 times daily, or 150mg, 2 times daily) as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency' data-fields on this form, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:05:56
Query 'Per CDM: Please verify the following: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency Fields' on this form, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:04:10

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please verify the following: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each. If appropriate, please update 'Dose per Administration' and 'Frequency Fields' on this form, and (2) Correct spelling of 'Name of Medication' to 'Bupropion HCL'. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:03:31
Query 'Per CDM: Please verify and update the following if appropriate: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each, (2) Correct spelling to 'Bupropion HCL'. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:00:04
User opened query 'Per CDM: Please verify and update the following if appropriate: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each, (2) Correct spelling to 'Bupropion HCL'. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:59:43
Query 'Per CDM: Please verify the following: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each, (2) correct spelling to Bupropion HCL. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:58:37
User opened query 'Per CDM: Please verify the following: (1) Confirm if dosage was taken at 100mg, 3 times daily, as this medicine is commonly divided into doses of no more than 150mg each, (2) correct spelling to Bupropion HCL. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 17:58:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 17:02:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Aug 2020 17:02:13
Data point term sent to Coder	System	06 Aug 2020 22:29:15

PRODUCTION RELEASE (v12.003
EAB) (1725)

1712 of 2081

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'BUPROPIOON HCL'	Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'DEPRESSION'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '300'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:54:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Megan Dandurand (b) (4)	06 Aug 2020 23:14:57
answered with 'DM Error' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:28:56
User entered 'UN UNK 2005'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56
	(b) (4)	

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:15:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:15:18
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:15:18
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:28:56
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:28:56

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: DULOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: CYMBALTA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:31:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 22:31:05
Data point term sent to Coder User entered 'CYMBALTA'	System Karen Knapp (b) (4) (b) (4)	06 Aug 2020 22:30:16 06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'DEPRESSION'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '60'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:54:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DM Error' (Site from System).	Megan Dandurand (b) (4)	06 Aug 2020 23:15:38
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:29:45
User entered 'UN UNK 2005'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:15:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:15:45
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:15:45
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:29:45
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:29:45

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: Per Medical History form, Subject had 'High Cholesterol' since UN UNK 1998. This medication with 'High Cholesterol' indication has recorded Start Date of UN UNK 2018. Please verify and confirm this medication start date is correct or update data if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:36:01
Query 'Per CDM: Per Medical History form, Subject had 'High Cholesterol' since UN UNK 1998. This medication with 'High Cholesterol' indication has recorded Start Date of UN UNK 2018. Please verify and confirm this medication start date is correct or update data if appropriate. Thank you.' answered with 'DATA IS CORRECT' (Site from DM).	Angie Kean (b) (4)	24 Dec 2020 17:22:07
User opened query 'Per CDM: Per Medical History form, Subject had 'High Cholesterol' since UN UNK 1998. This medication with 'High Cholesterol' indication has recorded Start Date of UN UNK 2018. Please verify and confirm this medication start date is correct or update data if appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:12:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:32:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:32:06
Data point term sent to Coder	System	06 Aug 2020 22:31:19
User entered 'ATORVASTATIN'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'HIGH CHOLESTEROL'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '80'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:55:00
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DM Error' (Site from System).	Megan Dandurand (b) (4)	06 Aug 2020 23:15:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:30:42
User entered 'UN UNK 2018'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:16:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:16:09
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:16:09
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:30:42
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:30:42

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: D3 - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:36:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	06 Aug 2020 22:36:08
Data point term sent to Coder User entered 'D3'	System Karen Knapp (b) (4)	06 Aug 2020 22:34:21 06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'GENERAL HEALTH'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '25'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'ug (ug)' reason for change: Data Entry Error	Angie Kean (b) (4)	02 Nov 2020 21:27:29
User entered 'Other (OTHER)'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 13:05:56
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	02 Nov 2020 21:27:34
User entered empty; reason for change Data Entry Error	(b) (4)	02 Nov 2020 21:27:29
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "ug" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 14:39:22
User entered 'MCG'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once daily (QD)'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:55:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'DM Error' (Site from System).	Megan Dandurand (b) (4)	06 Aug 2020 23:16:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:34:19
User entered 'UN UNK 2005'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:16:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:16:32
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:16:32
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:34:19
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:34:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: If appropriate, please verify and update 'Name of Medication' to include specific Isagenix product and respective active ingredients taken by the subject, since there are multiple Isagenix products, with various active ingredients, promoted for a wide range of indications including nutrition, anti-aging, brain and sleep support, cardiovascular heath, metabolism, immunity, and overall heath. Unless a medication is taken for Prophylaxis, the condition is expected to be recorded on the Medical History page. Please verify and update as appropriate, or confirm correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:37:10
Query 'Per CDM: If appropriate, please verify and update 'Name of Medication' to include specific Isagenix product and respective active ingredients taken by the subject, since there are multiple Isagenix products, with various active ingredients, promoted for a wide range of indications including nutrition, anti-aging, brain and sleep support, cardiovascular heath, metabolism, immunity, and overall heath. Unless a medication is taken for Prophylaxis, the condition is expected to be recorded on the Medical History page. Please verify and update as appropriate, or confirm correct. Thank you.' answered with 'INFORMATION IS UNABLE TO BE VERIFIED AS SUBJECT HAS EXPIRED. PLEASE ALSO NOT, MEDICATION IS LISTED AS PROPHYLAXIS' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:23:50

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: If appropriate, please verify and update 'Name of Medication' to include specific Isagenix product and respective active ingredients taken by the subject, since there are multiple Isagenix products, with various active ingredients, promoted for a wide range of indications including nutrition, anti-aging, brain and sleep support, cardiovascular health, metabolism, immunity, and overall health. Unless a medication is taken for Prophylaxis, the condition is expected to be recorded on the Medical History page. Please verify and update as appropriate, or confirm correct. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 18:39:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Sep 2020 07:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	08 Sep 2020 07:15:42
Data point term sent to Coder	System	04 Sep 2020 17:34:41
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	04 Sep 2020 17:34:10
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated name to include [unknown active ingredients] as this medication is a supplement' (Site from System).	Anya Penly (b) (4)	04 Sep 2020 17:34:10
Data point term sent to Coder	System	04 Sep 2020 17:33:40
User entered 'ISAGENIX [unknown active ingredients]' reason for change: Data Entry Error	Anya Penly (b) (4)	04 Sep 2020 17:33:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4)	26 Aug 2020 09:54:37
Data point term sent to Coder	System	06 Aug 2020 22:36:23
User entered 'ISAGENIX'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'GENERAL HEALTH'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '9' reason for change: Data Entry Error	Angie Kean (b) (4)	21 Oct 2020 12:54:36
User entered '5' reason for change: Data Entry Error	Angie Kean (b) (4)	21 Oct 2020 12:54:02
User entered '1'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Angie Kean (b) (4)	13 Nov 2020 19:47:29
User entered 'Other (OTHER)'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:47:00
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'Updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	13 Nov 2020 19:47:35
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	13 Nov 2020 19:47:29
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:47:01
User closed query 'Per DM CLR: Please review the unit and have each dose information be recorded into two separate loglines with the timing of administration noted in the frequency field. Please update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 10:20:09

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review the unit and have each dose information be recorded into two separate loglines with the timing of administration noted in the frequency field. Please update as appropriate, otherwise clarify.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	21 Oct 2020 12:54:09
User entered 'PILLS' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 12:54:02
User opened query 'Per DM CLR: Please review the unit and have each dose information be recorded into two separate loglines with the timing of administration noted in the frequency field. Please update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 02:29:57
User entered '4 PILLS/PM, 5 PILLS/AM'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once daily (QD)' reason for change: Data Entry Error	Angie Kean (b) (4)	21 Oct 2020 12:54:02
User entered 'twice daily (BID)'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	07 Aug 2020 14:55:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Megan Dandurand (b) (4)	06 Aug 2020 23:21:53
answered with 'DM Error' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	06 Aug 2020 22:36:12
User entered 'UN Aug 2019'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 23:21:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 23:21:57
User entered 'No (N)' reason for change: Data Entry Error	Megan Dandurand (b) (4)	06 Aug 2020 23:21:57
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 22:36:12
User entered empty.	Karen Knapp (b) (4)	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	21 Oct 2020 12:54:02
User entered '2'	System	06 Aug 2020 22:36:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '1'	System	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '804 (804)'	System	06 Aug 2020 22:36:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 12:52:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 12:52:38
Data point term sent to Coder	System	21 Oct 2020 12:51:27
Coding entries removed.	Angie Kean (b) (4)	21 Oct 2020 12:51:04
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:47:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 19:47:49
Data point term sent to Coder	System	25 Sep 2020 19:47:21
User entered 'influenza vaccine'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Prevention of Influenza infection).' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:48:51
Query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Prevention of Influenza infection).' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	21 Oct 2020 12:51:10
User entered 'FLU PREVENTION' reason for change: Data Entry Error	(b) (4)	21 Oct 2020 12:51:04
User opened query 'Per CDM: Indication is recorded as "Prophylaxis". Please update the indication of this medication to also include the medical condition/ diagnosis which needed this ConMed (Like: Prevention of Influenza infection).' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 16:15:43
User entered 'prophylaxis'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '1'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'dose'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'once (ONCE)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Intramuscular (INTRAMUSCULAR)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 5', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 22Sep2020, which is 22 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 8 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 11:38:49
Query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 5', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 22Sep2020, which is 22 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 8 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' answered with 'DATA IS CORRECT' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:25:32
User opened query 'Per CDM: As per section 6.4.3. of 'Protocol Amendment 5', 'Seasonal Influenza Vaccine' is not permitted within 14 days before or after any dose of IP. In this instance, Site reports 'Seasonal Influenza Vaccine' was given on 22Sep2020, which is 22 days after 2nd Dose, and is well within the allotted window per Protocol. However, since it is close to this narrow time-frame (only 8 days), kindly confirm date of 'Seasonal Influenza Vaccine'. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:58:31

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Seasonal influenza vaccine is not permitted within 14 days before or after any dose of IP, as per section 6.4.3. of Protocol Amend 5. In this instance, Site reports Seasonal Influenza Vaccine was given 22 days after 2nd Dose, which is well within the allotted window per Protocol. However, since it is close to this time-frame (only 8 days), kindly confirm date of Seasonal Influenza Vaccine is on 22Sep2020. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:55:11
User opened query 'Per CDM: Seasonal influenza vaccine is not permitted within 14 days before or after any dose of IP, as per section 6.4.3. of Protocol Amend 5. In this instance, Site reports Seasonal Influenza Vaccine was given 22 days after 2nd Dose, which is well within the allotted window per Protocol. However, since it is close to this time-frame (only 8 days), kindly confirm date of Seasonal Influenza Vaccine is on 22Sep2020. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 16:54:47
User entered '22 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '22 Sep 2020'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	25 Sep 2020 19:46:49

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY RAPIDMELTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:56
Data point term sent to Coder	System	12 Apr 2021 22:15:24
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:14:27
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
Data point term sent to Coder	System	02 Nov 2020 23:08:51
User entered 'ZICAM- COLD REMEDY TABLETS (ZINCUM ACETICUM / AINCUM GLUCONISUM)' reason for change: New Information	Angie Kean (b) (4) (b) (4)	02 Nov 2020 23:07:46
Data point term sent to Coder	System	02 Nov 2020 23:06:44
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	02 Nov 2020 23:06:28

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'UPDATED' (Site from System).	Angie Kean (b) (4)	02 Nov 2020 23:06:28
User entered 'ZICAM- COLD REMEDY' reason for change: New Information	Angie Kean (b) (4)	02 Nov 2020 23:06:23
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	01 Nov 2020 14:10:46
Data point term sent to Coder	System	27 Oct 2020 21:46:55
User entered 'ZICAM'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:14:27
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:14:27
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:23:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Subject was assessed for COVID-19 via illness visit, Symptoms recorded on symptom log, not an AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:16:25
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:46:08
User entered 'RUNNY NOSE'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '2'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:46:39

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY RAPIDMELTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:56
Data point term sent to Coder	System	12 Apr 2021 22:15:25
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:14:39
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
Data point term sent to Coder	System	02 Nov 2020 23:08:50
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	02 Nov 2020 23:08:07
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'UPDATED' (Site from System).	Angie Kean (b) (4) (b) (4)	02 Nov 2020 23:08:07

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ZICAM- COLD REMEDY TABLETS (ZINCUM ACETICUM / AINCUM GLUCONISUM)' reason for change: New Information	Angie Kean (b) (4)	02 Nov 2020 23:08:02
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	01 Nov 2020 14:10:47
Data point term sent to Coder	System	27 Oct 2020 21:47:57
User entered 'ZICAM'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:14:39
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:14:39
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:23:09
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptoms reported on symptom log, subject was assessed for COVID-19 via illness visit. No AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:17:15
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:46:19
User entered 'RUNNY NOSE'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '2'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:12

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY RAPIDMELTS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 09:51:57
Data point term sent to Coder	System	12 Apr 2021 22:15:25
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:14:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, PRODUCT: ZINC ACETATE;ZINC GLUCONATE, PRODUCTSYNONYM: ZICAM COLD REMEDY [ZINC ACETATE;ZINC GLUCONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 15:15:21
Data point term sent to Coder	System	02 Nov 2020 23:08:52
User closed query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	System	02 Nov 2020 23:08:24
Query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' answered with 'UPDATED' (Site from System).	Angie Kean (b) (4) (b) (4)	02 Nov 2020 23:08:24

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'ZICAM- COLD REMEDY TABLETS (ZINCUM ACETICUM / AINCUM GLUCONISUM)' reason for change: New Information	Angie Kean (b) (4)	02 Nov 2020 23:08:18
User opened query 'For coding purposes, references indicate different formulations for ZICAM . Please provide generic ingredients, complete, accurate trade name and update the term with your response' (Site from System).	Coder Import (b) (4)	01 Nov 2020 14:10:48
Data point term sent to Coder	System	27 Oct 2020 21:47:57
User entered 'ZICAM'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:14:50
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:14:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:37:24
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptoms reported on symptom log, subject was assessed for COVID-19 via illness visit. No AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:17:26
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:46:37
User entered 'RUNNY NOSE'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '2'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '19 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:47:55

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:05
Data point term sent to Coder	System	12 Apr 2021 22:14:23
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:13:42
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:11
Data point term sent to Coder	System	27 Oct 2020 21:48:57
User entered 'TYLENOL PM'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:42
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:13:42
User closed query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:19:04
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' answered with 'Subject reported taking this medication for this indication. recorded in source at illness visit. data is correct. ' (Site from DM).	Angie Kean (b) (4)	25 Mar 2021 21:19:44
User opened query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 19:17:49
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:39:17
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptoms reported on symptom log, subject was assessed for COVID-19 via illness visit. No AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:18:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:46:46
User entered 'FATIGUE'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '500'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '16 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:48:46

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:06
Data point term sent to Coder	System	12 Apr 2021 22:14:23
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:13:55
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:11
Data point term sent to Coder	System	27 Oct 2020 21:49:58
User entered 'TYLENOL PM'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:13:55
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:13:55
User closed query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:19:13
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' answered with 'noted in source subject reported this medication for this indication. data is correct. ' (Site from DM).	Angie Kean (b) (4)	25 Mar 2021 21:20:34
User opened query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 19:18:31
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:39:32
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptoms reported on symptom log, subject was assessed for COVID-19 via illness visit. No AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:18:19

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:46:56
User entered 'FATIGUE'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '500'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '17 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:49:15

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 22:28:05
Data point term sent to Coder	System	12 Apr 2021 22:14:23
Coding entries removed.	Breanna Galibert (b) (4) (b) (4)	12 Apr 2021 22:14:07
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL PM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:26:12
Data point term sent to Coder	System	27 Oct 2020 21:51:59
User entered 'TYLENOL PM'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	13 Apr 2021 15:10:46
Signature has been broken.	Breanna Galibert (b) (4)	12 Apr 2021 22:14:07
User entered 'covid-like illness' reason for change: New Information	Breanna Galibert (b) (4)	12 Apr 2021 22:14:07
User closed query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 07:19:35
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' answered with 'noted in source subject reported this medication for this indication. data is correct. ' (Site from DM).	Angie Kean (b) (4)	25 Mar 2021 21:20:39
User opened query 'Per CDM Re-query: Site response noted, however this medication is not indicated for 'Fatigue'. Please verify data and ensure to update 'Indication' field as appropriate, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 19:19:10
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:39:46
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' answered with 'Symptoms reported on symptom log, subject was assessed for COVID-19 via illness visit. No AE' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:18:29

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:47:04
User entered 'FATIGUE'	Breanna Galibert (b) (4) (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '500'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'mg (mg)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered empty.	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '0'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '18 Oct 2020'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'No (N)'	Breanna Galibert (b) (4)	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:52:46

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered empty.	System	27 Oct 2020 21:50:59

US3812060

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:52:46

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User closed query 'Per CDM: On 'ConProc Summary' form, 'Were any concomitant procedures performed?' is recorded as Yes, however, there are No concomitant procedures recorded. Please verify and update data as appropriate. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Dec 2020 11:45:54
Query 'Per CDM: On 'ConProc Summary' form, 'Were any concomitant procedures performed?' is recorded as Yes, however, there are No concomitant procedures recorded. Please verify and update data as appropriate. Thank you.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:35:40
User entered 'No (N)' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	24 Dec 2020 17:35:35
User opened query 'Per CDM: On 'ConProc Summary' form, 'Were any concomitant procedures performed?' is recorded as Yes, however, there are No concomitant procedures recorded. Please verify and update data as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 19:07:44
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	03 Sep 2020 12:37:32

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Visit 3 Day 57 (VISIT3)'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Visit Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Demographics](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Enrollment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Inclusion/Exclusion Criteria Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

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[Inclusion/Exclusion Criteria](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Medical History Summary](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Medical History](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Vital Signs](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Vital Signs - Dosing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Physical Examination](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Central Laboratory - Nasopharyngeal Swab](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Childbearing Potential](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Pregnancy Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Randomization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Immunogenicity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Saliva Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[COVID Diagnostic Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Symptom Log](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[COVID-19 Severity Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[COVID-19 Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Risk of Exposure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Safety Call](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '1'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Dosing Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[End of Study / Study Discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[All](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Date of missed or out of window visit or assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '27 Oct 2020'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Inclusion criteria not met/Exclusion criteria met](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Study Treatment not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Missed Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Missed Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Visit performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Assessment performed out of window](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Scheduled clinical visit performed as home visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

Generated On: 10 Jun 2021 09:52:46

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '1'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'SUBJECT IN CONVALESCENT PERIOD, SAFETY CALL DAY 85 NOT PERFORMED'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Clinical site closed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

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[Travel restrictions](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Quarantine due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Possible exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Exposure to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Presumption / confirmed COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '1'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Symptoms of COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Sponsor hold due to COVID-19](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

US3812060

Folder: COVID-19 Impact (1)

Form: COVID-19 Impact (1)

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[Participant decision](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '0'	Angie Kean (b) (4)	24 Dec 2020 17:37:57

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:52:46

Date of study discontinuation/completion (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '30 Nov 2020'	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: End of Study (1)

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Generated On: 10 Jun 2021 09:52:46

[Reason for discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Death (DEATH)'	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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If reason for discontinuation is Death, main cause of death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Lyly Dang (b) (4)	23 Apr 2021 15:18:29
User closed query 'Per CDM: "Myocardial Infarction" is listed as an AE with outcome of death therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 20:26:04
Query 'Per CDM: "Myocardial Infarction" is listed as an AE with outcome of death therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	20 Apr 2021 15:55:19
Signature has been broken.	(b) (4)	20 Apr 2021 15:55:03
User entered 'Adverse event (ADVERSE EVENT)' reason for change: Data Entry Error	Angie Kean (b) (4)	20 Apr 2021 15:55:03
User opened query 'Per CDM: "Myocardial Infarction" is listed as an AE with outcome of death therefore cause of death should be entered as Adverse Event, not Other. Please confirm and update Cause of Death to Adverse Event.' (Site from DM).	(b) (4), (b) (6)	17 Apr 2021 16:34:12
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Unknown (UNKNOWN)'	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:52:46

If main cause of death is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered empty.	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:52:46

Date of death (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '30 Nov 2020'	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

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[Was autopsy performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered 'Unknown (UNK)'	Lyly Dang (b) (4)	05 Dec 2020 17:00:30

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'USA-US111-2020-MRNA-1273-P301000017'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'lauren'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Larkin'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'clement'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Wadsworth'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '711 Old Ballas Rd Suite 105'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'St Louis'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'MO'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '63141'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered 'US'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '4'	System	09 Apr 2021 14:10:15
User entered '3'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '2'	System	28 Dec 2020 18:17:28
User entered '1'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'USA-US111-2020-MRNA-1273-P301000017'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'lauren'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Larkin'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'clement'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Wadsworth'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '711 Old Ballas Rd Suite 105'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'St Louis'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'MO'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '63141'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered 'US'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '4'	System	09 Apr 2021 14:10:15
User entered '3'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '2'	System	28 Dec 2020 18:17:28
User entered '1'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:52:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:25:18
User entered '05/Dec/2020 17:58'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:25:18
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered '1'	(b) (4), (b) (6)	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'USA-US111-2020-MRNA-1273-P301000017'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'lauren'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Larkin'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'clement'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Wadsworth'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '711 Old Ballas Rd Suite 105'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'St Louis'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'MO'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '63141'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered 'US'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '4'	System	09 Apr 2021 14:10:15
User entered '3'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '2'	System	28 Dec 2020 18:17:28
User entered '1'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:52:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 20:27:53
User entered '28/Dec/2020 18:17'	System	28 Dec 2020 18:17:28

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:39
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 20:27:53
User entered '1'	(b) (4), (b) (6)	28 Dec 2020 18:17:28

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'USA-US111-2020-MRNA-1273-P301000017'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'lauren'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Larkin'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'clement'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Wadsworth'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: Street](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '711 Old Ballas Rd Suite 105'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'St Louis'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'MO'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '63141'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered 'US'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '4'	System	09 Apr 2021 14:10:15
User entered '3'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '2'	System	28 Dec 2020 18:17:28
User entered '1'	System	05 Dec 2020 17:58:23

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:52:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '26/Mar/2021 14:24'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered '1'	(b) (4), (b) (6)	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[SAEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:50
Un-reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 18:23:47
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'USA-US111-2020-MRNA-1273-P301000017'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Serious

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Yes (Y)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'No (N)'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's First Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'lauren'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Larkin'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered 'clement'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'Wadsworth'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: Street

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '711 Old Ballas Rd Suite 105'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: City

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered 'St Louis'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Site Address: State](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
User entered 'MO'	System	26 Mar 2021 18:24:00

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
Reviewed for Safety.	(b) (4), (b) (6)	09 Apr 2021 14:10:05
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:31:39
Un-reviewed for Safety.	System	26 Mar 2021 18:24:00
Signature has been broken.	System	26 Mar 2021 18:24:00
User entered empty.	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 17:56:53
User entered '63141'	System	05 Dec 2020 17:52:09

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[Investigator Country](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
Reviewed for Safety.	(b) (4), (b) (6)	28 Dec 2020 18:17:16
User entered 'US'	System	05 Dec 2020 17:58:23

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Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form

Generated On: 10 Jun 2021 09:52:46

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
User entered '4'	System	09 Apr 2021 14:10:15
User entered '3'	System	26 Mar 2021 18:24:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:35:08
User entered '2'	System	28 Dec 2020 18:17:28
User entered '1'	System	05 Dec 2020 17:58:23

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Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:52:46

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Lyly Dang (b) (4)	12 Apr 2021 15:03:03
User entered '09/Apr/2021 10:10'	System	09 Apr 2021 14:10:15

US3812060

Folder: SAE USA-US111-2020-MRNA-1273-P301000017

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:52:46

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)	26 Apr 2021 21:20:50
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 20:52:43
User signature succeeded.	Lyly Dang (b) (4)	12 Apr 2021 15:03:03
User entered '1'	(b) (4), (b) (6)	09 Apr 2021 14:10:15